Disclaimer: This publication was co-funded by the European Union and Belgium. Its contents are the sole responsibility of Team Europe Support Structure (TESS) for the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) and do not necessarily reflect the views of the European Union, European Member States or other MAV+ stakeholders.

Working Papers present initial findings or ongoing research by the author(s) and are released to encourage dialogue on various topics related to TESS's work. Feedback on Working Papers is appreciated and can be sent via email to sofia.imad@enabel.be.

Working paper: Access conditions for public investment in the private pharmaceutical sector – What options for MAV+?

May 2025

Prepared by: TESS MAV+ // Key contact: Sofia Imad

Table of contents

Acknowledgements

We gratefully acknowledge the contributions of the distinguished panel of international experts who willingly shared their time and expertise to support this project: Miguel Campo LLopis, Team Leader, Private sector and Innovative Financing, Social Protection and Health unit, European Commission's Directorate-General for International Partnerships; Erika Dueñas Loayza, Technical Officer – Access to Medicines and Health Products Division, World Health Organization; Anna Lynch, Life Sciences Specialist, European Investment Bank; Nazeem Mohamed, Pharmaceutical Specialist, African Development Bank (AfDB); Chiluba Mwila, Technical Advisor – Talent Development, Africa CDC; Tim Roosen, Health Attaché, Belgian Ministry of Foreign Affairs; Maria Belen Tarrafeta Sayas, Research Fellow, Institute of Tropical Medicine; Els Torreele, Policy Associate, UCL Institute for Innovation and Public Purpose.

The author also would like to express their appreciation to Emma Shiffman and Moy Bracken, Access to Medicine Foundation; Sandra Akeza Haile Brugger, Africa CDC; Aurore Lambert, Agence Francaise de Développement (AFD); Rajinder Kumar Suri, Developing Countries Vaccine Manufacturers Network (DCVMN); Isabel Thywissen, Deutsche Investitions- und Entwicklungsgesellschaft (DEG); Sharif Egal and Sarah Spronk, Dutch Ministry of Foreign Affairs; Karim Karaki, ECDPM; Raffaele Cordiner, European Investment Bank (EIB); Anne-Sophie Travert, French Ministry of Foreign Affairs; Wilbert Bannenberg, Pharmaceutical Accountability Foundation (PAF); Malick Diallo, Proparco; Julia Hochberger and Aliénor Devalière, Wemos.

Finally, the author would like to thank colleagues in the Team Europe Support Structure for the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (MAV+) for feedback and input. This work benefited from valuable comments from Catherine Dujardin, Laura Moreno Reyes, and Carlos Leonidas Leiva.

The views expressed in this document are those of the author and do not necessarily reflect the views of any individual country or expert.

Introduction

Access to health products remains a critical issue today, with billions of people worldwide lacking adequate and consistent access to quality health products. Recent data indicates that about four and a half billion people are not fully covered by essential health services (WHO & IBRD, 2023). This multifaceted challenge includes the lack of access to medical countermeasures during outbreaks, medicines shortages caused by structural issues and vulnerabilities in the supply chain, rising prices of new pharmaceuticals, and lack of market incentives for older medicines (WHO, 2017). This lack of access can result in poor health outcomes, with diseases or conditions remaining undiagnosed, untreated, or sub-optimally treated.

To address this issue, UN Member States have set a target to achieve universal health coverage by 2030, aiming to provide financial risk protection, access to quality essential health-care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all (Sustainable Development Goal 3.8). In addition, many governments are supporting the development of a local pharmaceutical industry with the multiple objectives of improving access to health products, increasing health sovereignty and supporting economic development.

One such strategy is the African Union's strategy to establish regional manufacturing hubs and increase local production capacity of vaccines, medicines and diagnostics as part of their plan to produce 60% of their vaccines locally by 2040 (African Union & Africa CDC, 2022). To support this strategy, European actors established the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies (TEI MAV+), which includes the European Commission, Belgium, France, Germany, Netherlands, Luxembourg, Spain, Sweden, and the European Investment Bank as members. The initiative adopts a 360-degree approach, addressing health product supply, demand, and the enabling environment. Close to €2 billion has been committed, with more than half directed at health product manufacturers, either directly or through mechanisms such as Gavi's African Vaccine Manufacturing Accelerator (AVMA).

In parallel, the Team Europe MAV+ is working on improving access to health products in line with the Human Rights Council recommendation to promote collaborative efforts between States, the private sector, civil society, and other stakeholders to improve access to medicines, vaccines, and other health products. (Human Rights Council, 2024). Ensuring better access to health products is also a priority of multiple MAV+ members including Belgium, France, and Spain.

In this context, this note proposes to explore what factors, practices and conditions lead to more equitable access resulting from local manufacturing initiatives.

Financing local production

The pharmaceutical market in Africa has seen steady growth, estimated to reach US$33 billion in 2024 from US$25 billion in 2019. Approximately 600 manufacturers operate in Africa, concentrated in eight countries contributing to around 80% of total production (AfDB, 2021).

Compared to other sectors such as apparel, pharmaceutical manufacturers generally require substantial upfront investment (Damodaran, 2025) to support research and innovation, technology transfer, construction or upgrading of manufacturing facilities and compliance with the applicable pharmaceutical regulation. However, the availability of financial services on the continent remains quite limited for all industries. Commercial banks in most African countries offer loans with very high interest rates of 15-25% in local currency (UNIDO, 2019), while providing a low rate of domestic credit to the private sector (27% of GDP in Sub-Saharan Africa compared to 84% in the EU) (World Bank, 2024). In addition, Africa has experienced declines in foreign direct investment, overseas development aid, portfolio flows, and cross-border bank flows in recent years (EIB, 2024).

To address these financial challenges, the Africa CDC has prioritized access to finance and called for innovative partnerships and financing solutions to support African health product manufacturers (African Union & Africa CDC, 2022). As a result, various financing instruments have been developed at national, regional, and continental levels. Team Europe MAV+ has provided substantial support in multiple ways. This includes direct support to manufacturers, particularly vaccine producers. For instance, the European Investment Bank has provided a €75 million loan to the Institut Pasteur de Dakar (IPD) in Senegal for the construction of their new facility (EIB, 2022).

More recently, the launch of the Accelerating Human Development (HDX) guarantee has made up to €750 million available in the form of venture loans, corporate loans, and volume guarantees to cover interventions around insurance, primary health care, health R&D, digitalisation, talent and skills, and the production and delivery of health products (European Commission, 2025). However, experts interviewed during the analysis highlighted Development Finance Institutions (DFIs)'s limited understanding of the health sector and the specific needs of pharmaceutical companies. They emphasized that current financing instruments fail to meet the requirements of manufacturers and

suggested that these instruments should be developed collaboratively with manufacturers from the ground up to ensure they are better aligned with industry needs.

In parallel, Team Europe MAV+ also supports pull mechanisms such as Gavi's AVMA. This instrument aims to support the establishment of sustainable vaccine manufacturers and the development of drug substance platform technologies through milestone payments and per dose subsidies. Finally, Team Europe MAV+ also supports mechanisms such as pooled procurement mechanisms that contribute to a more predictable and sustainable demand.

Building an access ecosystem

The concepts of "access" and "equitable access" to health products frequently appear in political and policy documents within the public health and development sectors. However, there is no single, universally accepted definition. Access to health products goes beyond pricing and intellectual property (IP), encompassing broader challenges such as quality and accessibility, which were starkly highlighted during the COVID-19 pandemic. The right to health standards is based on a four-pillar framework: the AAAQ Concept, which stands for Availability, Acceptability, Accessibility, and Quality (WHO, 2017b).

Availability refers to the presence of health products in sufficient quantities at the appropriate time and place for all. Accessibility requires that health facilities, goods, and services must be accessible to everyone, considering non-discrimination, physical accessibility, economic accessibility (affordability), and information accessibility. Acceptability considers whether health products align with medical ethics, cultural and personal preferences, and sensitivities of the population. This is particularly relevant in the context of growing vaccine hesitancy and pushback against family planning policies. Quality ensures that health products meet established safety, efficacy, and manufacturing standards, providing individuals with reliable, high-standard products. More generally, equitable access is a component of the right to the highest attainable standard of physical and mental health, which is enshrined in several international legal instruments. The EU Global Health Strategy recommends improving equitable access to a full range of essential health services as a guiding principle following a human-rights based approach (European Commission, 2022).

Ensuring access to health products depends on a robust and well-functioning health system, as access is multidimensional and involves a wide range of stakeholders across the supply chain, from manufacturing to the point of care. The final price of a medicine is influenced not only by the manufacturer's pricing but also by several downstream factors,

including distributor margins, logistical complexity, market competition, national procurement capacity, and the availability of financial resources. Government policies—such as external reference pricing, price controls, and pooled procurement mechanisms—also play a critical role in determining medicine affordability. Likewise, ensuring medicine quality is a shared responsibility. Regulatory authorities must establish and enforce stringent pharmaceutical regulations, while manufacturers, wholesalers, pharmacies, and other supply chain actors are expected to adhere to established norms and standards, such as Good Manufacturing Practices (GMP) and Good Storage and Distribution Practices (GSDP). A strong health system is therefore essential—not only to coordinate and oversee these complex, interdependent processes but also to ensure that quality-assured, affordable health products reach all segments of the population in a timely and equitable manner.

Despite significant progress, major access gaps persist globally, with no harmonized strategy to address these issues comprehensively. The pandemic underscored the need for a paradigm shift to ensure equitable access to essential health products. In response to these challenges and to global supply chain disruptions, member states have adopted multiple strategies including the negotiation of a Pandemic Agreement and support to the local production agenda. The Pandemic Agreement recommends developing national or regional policies to attach public interest conditions to publicly funded grants, contracts, and other funding arrangements (WHO, 2025).

Private sector and access

Local manufacturing

The link between local production and access to health products has been a longstanding topic of discussion. According to a WHO report, although industrial development tools and measures can foster a profitable domestic industry, they do not necessarily ensure improved access to health products (WHO, 2011a). Factors such as the local ecosystem, population size, and the availability of human and financial resources influence the relationship between local production and access to health products. In addition, tensions may arise between industrial development objectives and the government's mandate to ensure affordable access to essential medicines (WHO, 2011b). However, based on interviews conducted for this analysis, local production, when implemented alongside complementary strategies, is viewed as a promising approach to addressing specific access barriers associated with globalized markets.

Some of the potential positive impacts of local production on access to health products are the following:

- **Strategic production:** National governments can incentivise local manufacturers to prioritize the production of essential medicines that are in short supply on their territory or critical for public health. This is particularly important during epidemics. A recent analysis showed that major local vaccine manufacturers, with the exception of Russia, outperformed their peers during the COVID-19 vaccination efforts, either by starting early or maintaining a consistent advantage throughout the pandemic (Schellekens, 2023).
- **Distribution networks:** Local firms typically have wider distribution networks, ensuring availability in remote areas. In Tanzania, for example, locally produced medicines are more likely to be available in remote areas because local firms rely on their own distribution mechanisms rather than on distributors based in major cities (Mujinja et al., 2014).
- **Supply chain resilience:** Local and shorter supply chains are more resilient to global disruptions, leading to a more stable supply and improved availability during pandemics.
- **Acceptable products:** Local manufacturers, whose core market is often domestic, can have a better access to national market information or better placed to collect market data. Moreover, they can design their products to be adapted to the local expectations and requirements, including providing appropriate packaging or leaflets in local languages.

On the other hand, here are the potentially negative impacts of local production on access to health products:

- **Price variability**: The impact on drug prices and affordability varies significantly by country based on local cost of production and national procurement and pricing policies. Research showed that in Ethiopia the government paid more for local products but applied a lower mark-up, yet patient prices were still higher than imports. However, in Tanzania, the government paid less for local products but applied a higher mark-up, leading to slightly higher patient prices for local products compared to imports (Ewen et al., 2017).
- **Quality concerns**: The risk is that the industrial agenda may conflict with the health agenda, leading to the neglect of quality standards in favor of supporting the national industry, as has been observed in India (Thakur & Reddy, 2022).

In addition, there are other access challenges that are not addressed by localizing production such as:

- **Market focus**: Local producers might focus on out-of-pocket markets, neglecting public markets.
- **Regional access**: There is no guarantee that production localized in one country will improve access in neighbouring countries.

Finally, local production of health products with restrictive technology transfer and intellectual property clauses can limit the availability of these products in neighboring countries and restrict the company's portfolio expansion.

Local or localized manufacturing

In addition, it is important to distinguish between local manufacturing, where ownership, control, and decision-making are based in the country or region, and "localized" manufacturing by subsidiaries of global companies. Supporting well-established multinational manufacturers is considered a low-risk investment to increase local production due to their track record, product portfolio, and technical expertise. This can be a first step towards developing a local production ecosystem to enhance local capacity and expertise.

However, Torreele and Sherwin (2024) argue that localized production by global companies is not sufficient in the pursuit of equitable access outcomes, specifically during a health crisis. They give the example of Johnson & Johnson's production of COVID-19 vaccines in South Africa, which were exported to Europe while South Africa struggled to access vaccines. In addition, global manufacturers investments are more unstable as the country is not the core business target. Recently, large pharmaceutical producers like GSK and Sanofi have discontinued operations in several African countries due to economic conditions (Access to Medicine Foundation, 2024). The Access to Medicine Foundation (2024) notes that while this shift does not mean companies no longer supply their products in these markets, it may impact the availability and affordability of essential health products.

Private sector and access – What is MAV+ currently doing?

MAV+ has been supporting the African private pharmaceutical sector through Development Financial Institutions (DFIs) and global health organizations. As per, OECD recommendations (2023), Official Development Assistance (ODA) support to the private sector must demonstrate development additionality, meaning it should deliver development impacts that would not have occurred without the partnership. It should also

be administered with the primary objective of promoting the economic development and welfare of developing countries. The following section will explore the mechanisms put in place to ensure access to health products.

DFIs are key stakeholders in Team Europe MAV+ and have been supporting pharmaceutical companies through a mix of loans, equity investments, guarantees, grants, and technical assistance. They have provided direct support to pharmaceutical manufacturers, enabling them to undertake specific projects or expand their operations. An example of this is the €500 million loan package provided to Aspen Pharmaceuticals in South Africa by a consortium including France's Proparco and Germany's DEG (IFC, 2024). In addition, DFIs have also launched schemes designed to support a broader range of manufacturers based on specific criteria. Examples include the European Investment Bank's €50 million initiative to strengthen local production of active pharmaceutical ingredients (APIs) in Africa.

The strategies of European DFIs regarding access to health products vary significantly. For instance, some operate under the assumption that any investment in health inherently improves access, without implementing specific access conditions; others have developed an access policy. For these, it mostly consists of access eligibility criteria to ensure funded companies have robust access policies and practices in place. These are included as part of their due diligence process and therefore reduce the transactional cost of the operation. For instance, Proparco has a point-based selection system to assess manufacturing companies' access strategy that includes geographical accessibility, financial accessibility, product or service quality, and alignment with national priorities (see Box 1).

Box 1. Proparco's access strategy

As part of their new strategy to reduce inequalities, Proparco has implemented a point-based system, reviewed every two years by health experts, to assess the access strategies of potential investees. Their selection criteria includes the following components:

- **Quality of healthcare delivery**: Established based on labels and certifications
- **Geographical accessibility:** Is the company active in zones identified as priority areas by the national health strategy or shown to have poorer health indicators?
- **Financial accessibility**: How do their prices compare to the public sector? Do they target the poorest 40% of the population?

In parallel, Team Europe MAV+ also provides financial support to pharmaceutical manufacturers through Gavi's African Vaccine Manufacturing Accelerator (AVMA). AVMA

employs tiered-level funding in its funding agreements to ensure that the financial support provided aligns with public health goals. Gavi has identified priority vaccine markets and platforms, and the level of funding increases based on the types of vaccines or vaccine platforms the manufacturers produce. AVMA also includes one selection criteria on quality: supported vaccines need to have received the WHO Prequalification (WHO-PQ).

Challenges

The current situation presents several challenges. The first challenge is that most instruments and organizations use different sets of eligibility criteria. This lack of harmonization has several consequences: it adds complexity and increases transaction costs for manufacturers, and it results in more work and suboptimal practices for funders. A more standardized access policy approach could raise awareness of access conditions and make the topic more mainstream in negotiations with the pharmaceutical sector.

A second challenge is that eligibility criteria are too stringent, risking the exclusion of many manufacturers. This creates high entry barriers and prevents smaller manufacturers from benefiting from these mechanisms. For example, obtaining WHO-PQ is a selection criterion to guarantee quality in some instruments, such as AVMA. This means that only companies with access to at-risk capital to finance product development and build a regulatory dossier can meet this high standard (Torreele & Sherwin, 2024). However, the current harmonized evaluation of National Regulatory Authorities (NRAs) based on maturity levels may allow for the use of alternative, phased quality selection criteria. For instance, manufacturers whose products are registered by NRAs with a maturity level 3 could be eligible for a portion of Milestone Payments, while full disbursement or additional funding could remain conditional on obtaining WHO Prequalification (PQ) as a higher quality benchmark.

The third challenge is that funders are reluctant to add too many eligibility criteria when the pool of companies that apply for funding is already small. This reluctance is partly due to hesitancy from global companies to invest in the pharmaceutical industry in Africa, but the more pressing issue is the mismatch between the need for financing and existing instruments. Experts interviewed during this analysis emphasized that manufacturers have diverse needs, requiring different types of financing tools based on their specific investments. For example, a manufacturer needing a GMP upgrade has different financing needs than one building an R&D pipeline. However, existing instruments are generally tailored to larger infrastructure projects and do not meet the industry's requirements, which include projects that may be lower cost or require longer repayment periods.

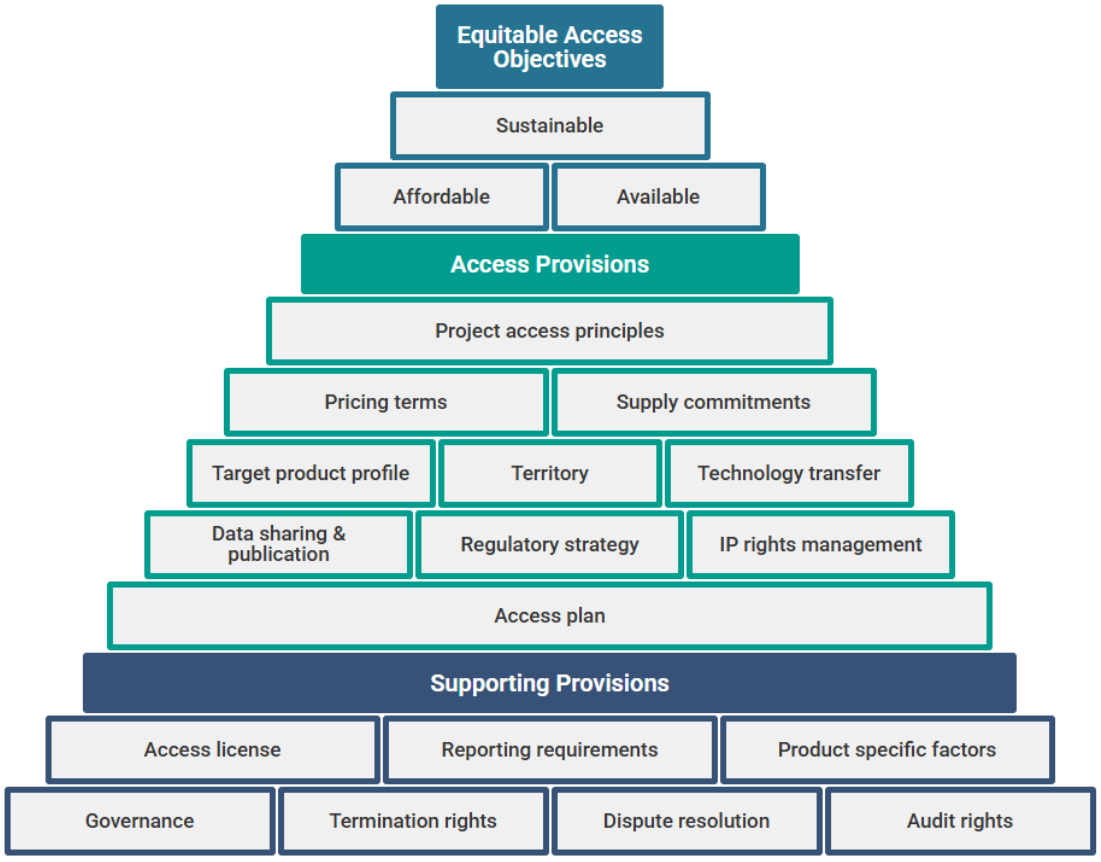
Financing and access – what are others doing?

The question of ensuring the public impact of public funding through private initiatives has been raised by many stakeholders. To try to answer this question, we explored other mechanisms that can enhance the impact of Team MAV+ investments.

Contractual Clauses

Contractual clauses in funding agreements ensure that recipients comply with specific conditions, such as pricing strategies or distribution requirements. Product Development Partnerships (PDPs), like the Drugs for Neglected Diseases Initiative (DNDi), frequently use these clauses to guarantee that health products they help develop remain affordable and accessible. The "Equitable Access Pyramid" below (Telford & Barnes-Weise, 2022) illustrates the complexity and variety of the components that can be considered when drafting an agreement.

Figure 1. Equitable Access Pyramid



Source: Telford & Barnes-Weise, 2022

For each component, there are multiple strategies. For example, for pricing strategies, there are two broad approaches: fixed or flexible prices. In the fixed price category, donors implement various options ranging from price caps to "COGS +" strategies. For instance, Sanofi and DNDi agreed on a price cap of $1 for adults and $0.50 for children for the anti-malarial ASAQ (Bompart et al., 2011). On the other hand, CEPI aims to limit the price of vaccines for low- and middle-income countries (LMICs) using what's known as the COGS+ approach. This means the price cannot exceed the actual cost of making the vaccine—called the Cost of Goods Sold (COGS)—plus a small, agreed-upon percentage to allow for some profit. In addition, CEPI requires that any vaccines purchased by CEPI, GAVI, or their partners must not be priced higher than the lowest price the vaccine maker charges any other buyer in an LMIC. Where possible, CEPI also secures the right to audit COGS (CEPI, 2023).

The price cap strategy has been criticized for stifling market dynamics. By fixing a maximum price, it does not encourage manufacturers to explore alternative production options that could reduce the COGS of the products. Regarding the COGS+ strategy, monitoring COGS can be challenging for partners as these calculations are complex and commercially sensitive (Telford & Barnes-Weise, 2022). Other approaches to pricing include contractual mentions of fair pricing without setting a precise limit, intellectual property (IP) management and licensing strategies to allow some level of competition, as well as transparency of pricing elements.

Box 2 - Generic companies and access

Existing contractual clauses on access primarily address the introduction of innovative medicines and the associated risks regarding affordability and availability. These clauses are mainly relevant to innovative pharmaceutical companies with less emphasis on generics companies, which typically follow a low-cost/high-volume strategy.

However, the Access to Medicine Foundation (2023) notes that while the low-cost/high-volume strategy can expand global access, significant challenges persist regarding the affordability and availability of generic medicines in LMICs. For instance, even if a generic medicine is priced lower than its branded counterpart, it may still be unaffordable for many patients, particularly those who rely on the private market and pay out-of-pocket. In addition, availability can be a barrier; companies may prioritize lucrative markets and not offer their products or only a limited sub-set in many LMICs.

Considering these distinct business models is essential when formulating strategies to guarantee conditions are applicable and impactful.

In their analysis of access strategies during R&D in the health sector, Rius Sanjuan et al. (2024) examined the access policies and practices of 40 funders and innovators and found a significant lack of harmonization. Firstly, each funder has a different definition of access. Secondly, they analyzed policies and practices based on two pillars: access policy (including acceptability, affordability, availability, and open innovation) and access practices (including governance, stakeholder management, implementation, and monitoring and evaluation). They found that the most common elements addressed were affordability and availability, and no access policy surveyed covered all eight elements.

Their recommendations included creating global norms, establishing a peer exchange space, strengthening access policies, and evaluating which measures are most effective in improving access. They also called for the development of model access policies, checklists, and roadmaps for funders and innovators to implement these elements, with the potential for funders to identify agreed minimum standards for access planning during R&D.

Common good approach

The mRNA Hub was established by the WHO during the COVID-19 pandemic to facilitate the transfer of mRNA technology to vaccine manufacturers in low- and middle-income countries (LMICs). The hub aims to help these countries produce mRNA vaccines at scale and in accordance with international standards. The mRNA vaccine platform offers several advantages, including rapid adaptation to variants and a smaller industrial footprint. The hub supports this effort by providing training, technology transfer materials, equipment, and technical assistance to partners. It is based on a common good approach, building on a needs-driven R&D portfolio for end-to-end production (WHO, 2023). While there has been criticism regarding its weak conditions around product affordability and its centralized structure (Herder & Benavides, 2024), the experts we interviewed generally considered it a successful model for manufacturing with an access lens.

Labels

We can also learn from other sectors, such as the gender space. The 2X Criteria, launched at the 2018 G7 Summit in Canada, significantly advanced gender lens investing by unifying investors under one framework (2X Challenge, 2024). The 2X Criteria assess and monitor investments that enhance women's leadership, employment, finance, enterprise support, and economic participation. The 2X Criteria can be used by any investor or financial institution to set targets and self-report alignment. This includes impact investors, development finance institutions, international finance institutions, multilateral

development banks, pension funds, endowments, asset managers, private equity firms, individual investors, and other capital providers.

Widely adopted, the 2X Criteria has been integrated into major finance standards. Since 2018, they have mobilized over US$33 billion to advance women's economic empowerment (2X Challenge, 2024). A potential criteria for pharmaceutical companies could be derived from the Access to Medicine Foundation's decade-long work in evaluating their access strategies and policies. This evaluation uses a point-based approach based on over 20 criteria, as detailed below (Access to Medicine Foundation, 2024). This would need to be adapted to overcome its shortcomings, including limited transparency, reliance on proxy access indicators, and unaddressed issues (McCoy & Milsom, 2025).

Figure 2. Access to Medicine methodology

Governance of access (15%)	Governance structures & incentives	**Product delivery (55%)**	Registration performance
	Access-to-medicine strategy & outcome		Access strategies: Ad hoc donations / Long-term donation programmes /Supranational products
	Responsible business practices		Access strategy quality & outcomes: Healthcare practitioner- and self- administered products
	Ethics, risk & compliance		Patent status disclosure
	Incidence of breaches		IP sharing
	Trade policy: IP & access to medicine		Quality and geographic coverage of access-oriented licensing
	Measuring & reporting patient reach		Ensuring continuous supply
R&D (30%)	R&D pipeline: prioritized diseases		Reporting substandard and falsified medical products
	R&D pipeline: other diseases		Capacity building in manufacturing
	Planning for access: Framework		Capacity building in supply chain management
	Planning for access: Project-specific plans for prioritised diseases		Health system strengthening
	Planning for access: Project-specific plans for other diseases		Inclusive business models
	Disclosure of resources dedicated to R&D		
	Capacity-building in R&D		

Source: Access to Medicine Foundation, 2024

Conclusion

As this working paper demonstrates, achieving equitable access to health products through public investment in the private pharmaceutical sector is both a pressing need and a complex challenge. While public funding is increasingly directed toward strengthening local manufacturing capacity in Africa, especially through initiatives such as Team Europe MAV+, the access outcomes of these investments cannot be left to chance. Experience shows that industrial growth alone does not guarantee improved availability, affordability, or quality of health products. Instead, access must be intentionally designed, supported, and monitored through robust tools and frameworks.

The examples reviewed throughout this paper highlight a variety of promising approaches—from access eligibility criteria in development finance institutions to tiered funding strategies and contractual clauses in public-private partnerships. These tools can serve to align public funding with public health goals, provided they are deployed consistently and adapted to the diverse business models of pharmaceutical companies. Importantly, these mechanisms must be accessible and realistic for a wide range of manufacturers, including smaller and regional players.

Yet, the field remains fragmented. A lack of harmonized definitions, metrics, and conditions for access undermines both effectiveness and efficiency. The diversity of standards, requirements, and expectations creates high transaction costs and limits the scale and sustainability of impact. There is an urgent need for greater coordination among donors, DFIs, implementing partners, and regulators to develop a common framework for access conditionalities that can be flexibly applied across geographies and contexts. Such a framework should incorporate differentiated approaches for generic versus innovative manufacturers, establish phased benchmarks for quality assurance, and embed principles of transparency, affordability, and equity into funding agreements.

As we look to the future, building a shared understanding of access impact and deploying fit-for-purpose conditionalities must be central to all efforts to support local manufacturing. This requires not only stronger technical tools but also a culture of collaboration—among governments, funders, manufacturers, and civil society. Only through coordinated, intentional strategies can we transform public investments into meaningful improvements in access, health outcomes, and health equity for all.

Annex: List of references

2X Challenge. (2024). 2X Criteria. Retrieved April 11, 2025, from https://www.2xchallenge.org/criteria

Access to Medicine Foundation. (2023). *Generic & Biosimilar Medicines Programme 2023*

Access to Medicine Foundation. (2024). *Access to Medicine Index 2024*

African Development Bank. (2021). *AfDB's Pharmaceutical Industry Support Vision and Action Plan for Africa*.

African Union, Africa CDC. (2022). *Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action*

Bemelmans, M. & Mulumba, M. (2024, December 18). Vaccines for Africa by Africa. *Think Global Health*. https://www.thinkglobalhealth.org/article/vaccines-africa-africa

Bompart, F., et al. (2011). Innovative public-private partnerships to maximize the delivery of anti-malarial medicines: lessons learned from the ASAQ Winthrop experience. *Malaria Journal*, 10, 143. DOI:10.1186/1475-2875-10-143

CEPI. (2018). *Equitable Access Policy*

CEPI. (2023). Equitable Access Framework

Damodaran, A. (2025). *Capital Expenditures by Sector (US).* Retrieved from https://www.stern.nyu.edu/~adamodar/pc/datasets/capex.xls

DNDi. (2020). *Access Policy*.

DNDi. (n.d.). *Development collaboration and license agreement*

European Commission. (2022). *EU Global Health Strategy: Better Health for All in a Changing World*. Publications Office of the European Union.

European Commission. (2025). *Accelerating Human Development.* Retrieved from https://international-partnerships.ec.europa.eu/funding-and-technical-assistance/accelerating-human-development_en

European Investment Bank. (2024). *Finance in Africa: Unlocking investment in an era of digital transformation and climate transition*. https://www.eib.org/en/publications/finance-in-africa-2024

European Investment Bank. (2022, June 2). *EIB provides €75 million to Institut Pasteur de Dakar for new vaccine manufacturing facility.* Retrieved from https://www.eib.org/en/press/all/2022-257-eib-provides-eur-75-million-to-institut-pasteur-de-dakar-for-new-vaccine-manufacturing-facility.

Ewen, M., Kaplan, W., Gedif, T., Justin-Temu, M., Vialle-Valentin, C., Mirza, Z., Regeer, B., Zweekhorst, M., & Laing, R. (2017). Prices and availability of locally produced and imported medicines in Ethiopia and Tanzania. *Journal of Pharmaceutical Policy and Practice*, 10(7).

FIND. (2018). *Global Access Policy*

Gates Foundation. (n.d.). *Global Access Statement.* https://www.gatesfoundation.org/about/policies-and-resources/global-access-statement

Herder, M., & Benavides, X. (2024). 'Our project, your problem?' A case study of the WHO's mRNA technology transfer programme in South Africa. *PLOS global public health, 4(9), e0003173*. https://doi.org/10.1371/journal.pgph.0003173

Human Rights Council. (2024). Analytical study on key challenges in ensuring access to medicines, vaccines and other health products in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. *Annual report of the United Nations High Commissioner for Human Rights and reports of the Office of the High Commissioner and the Secretary-General*. United Nations High Commissioner for Human Rights.

Hunt, P. (2008). Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. In *63rd session of the UN General Assembly*.

International Finance Corporation. (2024, September 3). *IFC, Proparco, DEG, and DFC support Aspen to strengthen Africa's pharmaceutical sector*. Retrieved from https://www.ifc.org/wps/wcm/connect/news_ext_content/ifc_external_corporate_site/news+and+events/news/ifc-proparco-deg-dfc-support-aspen.

Junod Moser, D., Boulet, P., Childs, M., Shieh, M., & Pécoul, B. (2023). Striking fair deals for equitable access to medicines. *Journal of Intellectual Property Law & Practice*, 18(4), 323–335. https://doi.org/10.1093/jiplp/jpad025

McCoy, D., & Milsom, P. (2025). Corporate accountability: A case study of the Access to Medicine Index. *United Nations University International Institute for Global Health*. https://doi.org/10.37941/PB/2025/1

Mujinja, P. G., Mackintosh, M., Justin-Temu, M., & Wuyts, M. (2014). Local production of pharmaceuticals in Africa and access to essential medicines: 'Urban bias' in access to imported medicines in Tanzania and its policy implications. *Globalization and Health, 10*(12). https://doi.org/10.1186/1744-8603-10-12

Organisation for Economic Co-operation and Development. (2023). *Private sector instruments – Batch 1 topics* (DCD/DAC(2023)22/FINAL). OECD Publishing.

Rius Sanjuan, J., Crockett, R., Reid, J., & Chikwanha, I. (2024). Planning for access during research and development. *Uniting Efforts for Innovation, Access and Delivery*.

Schellekens, P. (2023, September 7). *Local vaccine manufacturing pays off*. Center for Global Development. Retrieved from https://www.cgdev.org/blog/local-vaccine-manufacturing-pays.

Telford, B., & Barnes-Weise, J. (2022, November 21). *Equitable access obligations in funding agreements: Best practice considerations*. Global Healthcare Innovation Alliance Accelerator.

Thakur, D., & Reddy, P. (2022). *The Truth Pill: The Myth of Drug Regulation in India*. Simon & Schuster India.

Torreele, E., Wolfe, D., Kazatchkine, M., Sall, A., Ruxrungtham, K., Fitchett, J. R. A., Liu, J., Kobinger, G., Vaca-González, C., Gómez, C., Terblanche, P., Swaminathan, S., Olliaro, P., & Clark, H. (2023). From private incentives to public health need: Rethinking research and development for pandemic preparedness. *The Lancet Global Health, 11*(10), e1658-e1666. https://doi.org/10.1016/S2214-109X(23)00328-5

Torreele, E., & Sherwin, H. (2024). Health equity requires transformational change: Financial incentives based on worn-out market thinking will not deliver. *PLOS Global Public Health*, 4(4), e0003147. https://doi.org/10.1371/journal.pgph.0003147

UCL Institute for Innovation and Public Purpose. (2018). The people's prescription: Re-imagining health innovation to deliver public value. *IIPP Policy Report, 2018-10*.

UNIDO. (2019). *Pharmaceutical industry in Sub-Saharan Africa: A guide for promoting pharmaceutical production in Africa*.

Wemos, Afya Na Haki, Health Development Initiative, Great Lakes Initiative for Human Rights and Development. (2024). *BioNTech Africa: in the region, but also for and by the region?*

Wemos. (2024). *Why it is important to attach conditions to investments in regional production of health products*.

World Bank Group. (2024). *Domestic credit to private sector by banks (% of GDP) - European Union, Sub-Saharan Africa.* Retrieved from https://databank.worldbank.org/source/international-financial-statistics.

World Health Organization. (2011a). *Local Production for Access to Medical Products: Developing a Framework to Improve Public Health*

World Health Organization. (2011b). *Local production and access to medicines in low- and middle-income countries A literature review and critical analysis*

World Health Organization. (2017a). *Towards Access 2030: WHO Essential Medicines and Health Products Strategic Framework 2016-2030*. Geneva: World Health Organization.

World Health Organization. (2017b). Country support package for equity, gender and human rights in leaving no one behind in the path to universal health coverage. https://www.who.int/gender-equity-rights/knowledge/human_rights_tool/en/

World Health Organization. (2021). *Forum Discussion Paper: Aligning incentives for pharmaceutical innovation to achieve fair pricing*

World Health Organization. (2023). *The mRNA Vaccine Technology Transfer Hub: A pilot for transformative change for the common good?* The WHO Council on the Economics of Health for All. https://www.sciencedirect.com/science/article/pii/S2214109X23003285

World Health Organization, International Bank for Reconstruction and Development / The World Bank. (2023). *Tracking universal health coverage: 2023 global monitoring report.* Geneva: World Health Organization.

World Health Organization. (2025). *Proposal for the WHO Pandemic Agreement*.