Boosting Health Product Manufacturing Capacity in Africa: Recommendations for the 2024 G7 Presidency

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Contents

List of Abbreviations

ACT-A	Access to COVID-19 Tools Accelerator
AfCFTA	African Continental Free Trade Area
Afreximbank	African Export-Import Bank
Africa CDC	Africa Centres for Disease Control and Prevention
AMA	African Medicines Agency
AMC	Advance Market Commitment
API	Active Pharmaceutical Ingredient
AU	African Union
AUDA-NEPAD	African Union Development Agency
AVMA	African Vaccine Manufacturing Accelerator
AVMI	African Vaccine Manufacturing Initiative
CEPI	Coalition for Epidemic Preparedness Innovations
DS	Drug Substance
EC	European Commission
EU	European Union
FFA	PAVM Framework for Action
G7	Group of 7
GF	The Global Fund to fight AIDS, Tuberculosis and Malaria
IFFIm	International Finance Facility for Immunisation
IP	Intellectual Property
IPD	Institut Pasteur de Dakar
LMICs	Low- and middle-income countries
LPA	Local Production and Assistance
MAV+	Manufacturing and Access to Vaccines, Medicines and Health Technologies
MCDP	MCM Delivery Partnership for equitable access
MCM	Medical Countermeasure
MoU	Memorandum of Understanding
MPP	Medicines Patent Pool
MS	Member State
NRA	National Regulatory Authority
ODA	Official Development Assistance
PAVM	Partnerships for African Vaccine Manufacturing
PMPA	Pharmaceutical Manufacturing Plan for Africa
PPM	Pooled Procurement Mechanism
PPR	Prevention, Preparedness and Response
R&D	Research and Development
TB	Tuberculosis
TEI	Team Europe Initiative
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNIDO	United Nations Industrial Development Organisation
WB	World Bank
WHA	World Health Assembly
WHO	World Health Organisation
WTO	World Trade Organisation

Policy Recommendations for Italy's 2024 G7 Presidency

Political commitment

1. State renewed support to building African health product manufacturing capacity, clearly referencing AU efforts (PAVM) and existing initiatives, in view of creating a regional production ecosystem.

2. Bring this commitment to the multilateral level too, pushing for the explicit inclusion of this objective in the text of the Pandemic Treaty.

Define the issue

3. Commit to supporting manufacturing capacity building in the African health product sector as a whole, including vaccine production.

Intellectual property

4. Pledge collective support to MPP, especially the mRNA Technology Transfer Hub Programme.

5. Agree to a TRIPS waiver on priority health products, which are to be identified in partnership with affected communities.

6. Include access considerations in R&D funding and procurement agreements.

Financial support for health product manufacturing

7. Support an AMC-like instrument with a clear, realistic timeline for boosting vaccine manufacturing in Africa.

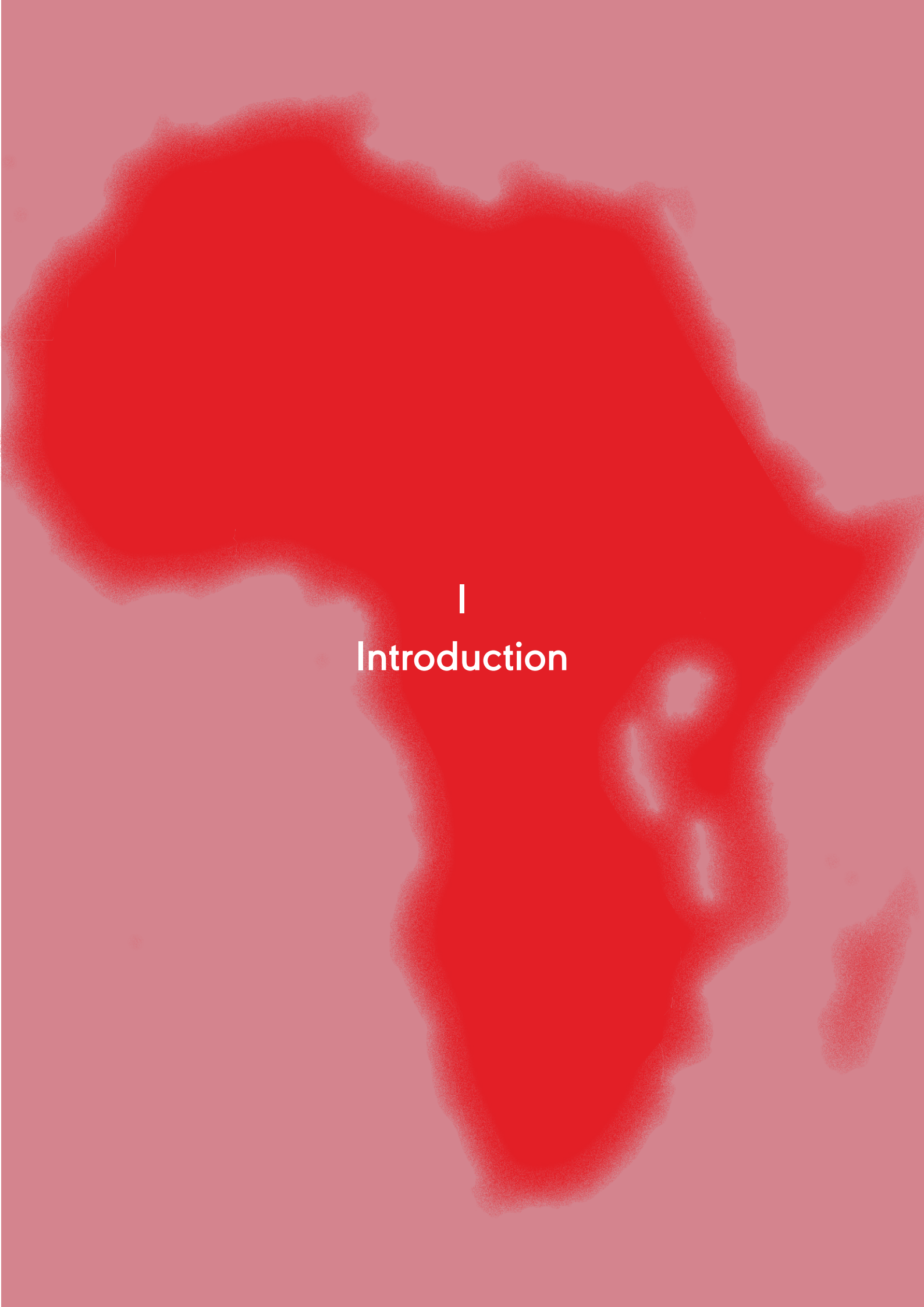
8. Include local manufacturing capacity building in the next Pandemic Fund call for proposals.

9. Include reference to supporting African health product manufacturing capacity and increasing actor coordination when announcing pledges for CEPI, Gavi, GF, MPP and UNITAID.

10. Devise de-risking tools to foster private sector investment in African health product manufacturing in additional development finance institutions and multilateral development banks.

International financial architecture

11. Support reforms of the current sovereign debt system to avoid trade-offs between debt servicing and social welfare in LMICs.



I
Introduction

The Covid-19 pandemic ceased to be a public health emergency on 5 May 2023.[1] Although the world's attention had long moved to other crises, the deep rethinking prompted in the global health sector has not stopped.

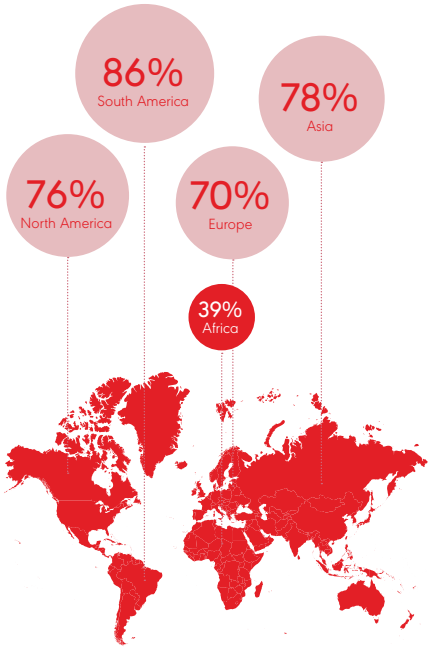
A series of initiatives are currently drawing on the lessons learnt from the Covid-19 pandemic to avoid history repeating itself in the form of slow and disjointed public policy responses to the sudden crisis. **Pandemic prevention, preparedness and response (PPR)** was the object of a September 2023 UN General Assembly High-Level Meeting,[2] in the context of ongoing negotiations on a so-called Pandemic Treaty that started in December 2021.[3] In addition, a new Directorate-General at the European Commission is now working exclusively on this issue, the Health Emergency Preparedness and Response Authority (DG HERA).[4]

Another pandemic lesson that policymakers and practitioners are absorbing is **health inequality**, driven by unequal access to healthcare. **Vaccine nationalism** led to a faster distribution of doses and higher vaccination rates in high-income countries compared to low-income ones. As a result, as of September 24, 2023, 32.6% of people received at least one dose of Covid-19 vaccine in low-income countries, compared to 66.4% in lower-middle income ones, 79.9% in higher-income countries and 83.5% in upper-middle income countries.[5] In a regional breakdown, the African continent fares the lowest on the vaccination score – 39% of its people have either completed the full vaccination cycle or are partially vaccinated, in stark contrast to Europe's 70%, North America's 76%, Asia's 78% and South America's 86%.[6]

While Covid-19 might not currently represent as serious a health threat as it did in 2020, these figures lead to two considerations. First, countries will be led to protect their **national interest** first and foremost in a crisis of such a scale, leaving little to international solidarity efforts, as the fate of COVAX showed.[7] Second, supply chains in health products are structured in such a way that many countries, especially low-income ones, are severely exposed to disruptions, since they are significantly **dependent on imports** for critical goods. Consequently, the case for local production of health products has become increasingly urgent. This would not only enable greater levels of **health security**, but it could also be a steppingstone towards **addressing the different incidence of diseases** worldwide and achieving **Universal Health Coverage**.[8]

The call has been particularly strong for the **African continent**, where Covid-19 vaccine nationalism resembled the dynamics of the AIDS epidemic two decades earlier.[9] In particular, the fact that 70 to 90% of drugs consumed on the continent are imported,[10] as well as the high incidence rate of diseases both curable and region-specific, make a compelling case for strengthening the continent's **health product manufacturing capacity** – not simply for vaccines, but for diagnostic, treatment and pharmaceutical products at large. Multiple initiatives have been launched at the regional and international level to increase the African continent's production of vaccines, diagnostics and drugs to boost its health security and close existing inequalities, targeting different areas in the manufacturing process. What are these initiatives, and to what extent are they **complementary**? Is there room for increased **synergies** between the involved actors? And how could the Group of 7 (**G7**) contribute to keeping this goal high on the international policy agenda?

This report will try to answer these questions by first illustrating the current status of local health product manufacturing in Africa and its challenges. It will then look at the policy frameworks that support strengthening local manufacturing capacity on the continent, as well as the initiatives by regional and international actors to do so.[11] Based on this analysis, it will provide recommendations for the 2024 Italian Presidency of the G7 to accelerate progress towards the localisation of health product manufacturing on the continent.[12]



SHARE OF PEOPLE VACCINATED AGAINST COVID-19

(as of 24 September 2023)

Source: Edouard Mathieu et al. *"Share of People Vaccinated Against COVID-19"*,cit. Elaboration by IAI

II

Health Product Manufacturing in Africa

The market

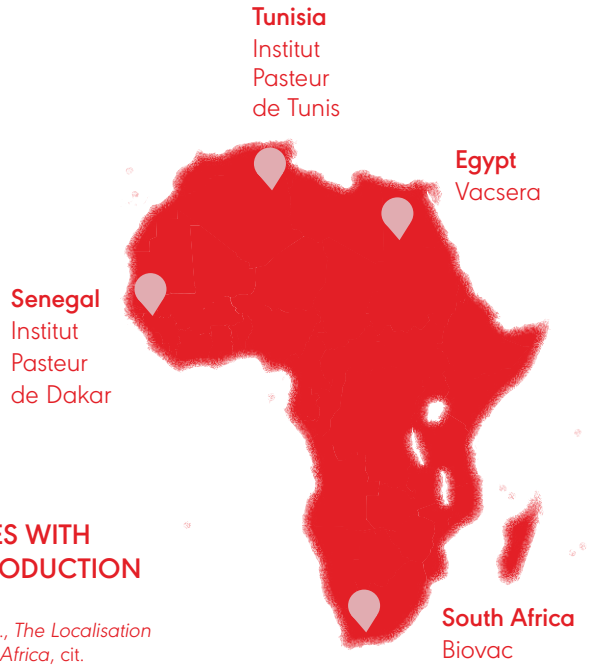
Data on the African health product industry can help understand the scale of the challenge of boosting local manufacturing in this sector. The African continent accounts for only 3% of global pharmaceutical production, despite hosting 17% of the world population.[13]

Research predating the Covid-19 pandemic revealed that 375 drug manufacturers served a 1.3 billion population, with a market value of around USD 14 billion. These figures stand in stark contrast to those for two similarly sized health product markets: China in 2019 hosted 5,000 drug manufacturers, worth USD 120 billion; India counted 10,500 manufacturers and a USD 19 billion market value.[14]

In addition to the low numbers, other features make the health product industry relatively nascent on the continent. First, production sites are **unequally distributed**: North Africa accounts for a larger share of manufacturers, and pre-pandemic, 9 out of 46 sub-Saharan countries hosted the remaining ones, with "a relatively sizable industry" that could be found only in Kenya, Nigeria and South Africa. Second, most of these companies' operations are **limited in scale**, producing mainly for the national and sometimes regional markets. Third, and relatedly, in 2019 **only 3 manufacturers produced Active Pharmaceutical Ingredients** (APIs); the largest majority acquire them from other manufacturers to then create finished health products. Moreover, 2019 figures reported that "up to a hundred manufacturers in sub-Saharan Africa" operated only in the packaging sphere.[15]

More recent, pandemic-era analysis paints a similar picture, though with slightly updated figures. While the number of overall drug manufacturing plants is higher (649),[16] the **geographical distribution** remains rather **unequal**, with South Africa, Egypt and Nigeria accounting for the highest number of plants (figure 1).

Focusing more specifically on **vaccine production**, which has received particular attention in the wake of the pandemic (see sections below), only **4 countries** in Africa have established operations in this sphere – Egypt (Vacsera), Senegal (Institut Pasteur de Dakar, IPD), South Africa (Biovac) and Tunisia (Institut Pasteur de Tunis). In terms of API production for drugs and vaccines' active drug substances, manufacturing capacity remains limited. South Africa, for example, "produces APIs for paracetamol, codeine and a cancer drug"; other countries *could* produce active drug substances; but there is still a **significant reliance on** (mainly Chinese) **APIs** for medicines.[17]



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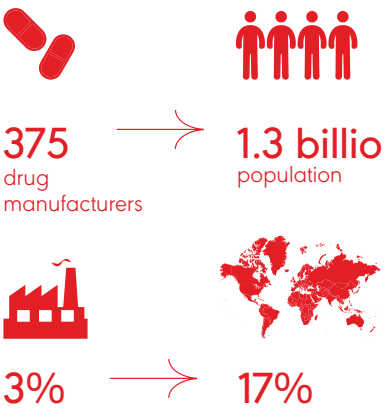
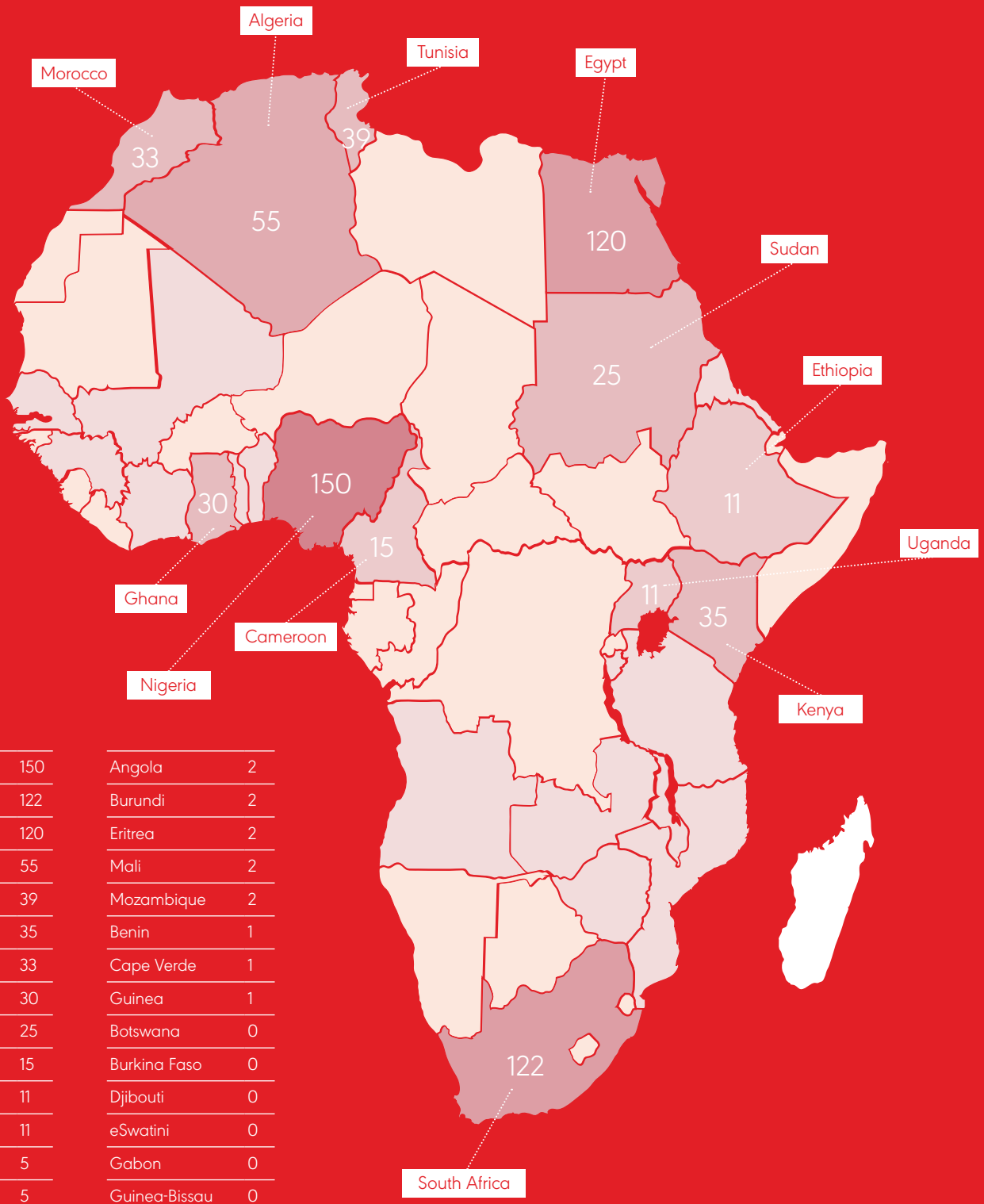
AFRICAN COUNTRIES WITH ACTIVE VACCINE PRODUCTION OPERATIONS
Source: Geoffrey Banda et al., *The Localisation of Medical Manufacturing in Africa*, cit.



AFRICAN HEALTH PRODUCT INDUSTRY
Source: Michael Conway et al., *"Should Sub-Saharan Africa Make Its Own Drugs?"*, cit.

African pharmaceutical manufacturing plants



Nigeria	150
South Africa	122
Egypt	120
Algeria	55
Tunisia	39
Kenya	35
Morocco	33
Ghana	30
Sudan	25
Cameroon	15
Ethiopia	11
Uganda	11
Ivory Coast	5
Senegal	5
Zambia	5
Zimbabwe	5
Tanzania	4
Malawi	3
Togo	3

Angola	2
Burundi	2
Eritrea	2
Mali	2
Mozambique	2
Benin	1
Cape Verde	1
Guinea	1
Botswana	0
Burkina Faso	0
Djibouti	0
eSwatini	0
Gabon	0
Guinea-Bissau	0
Lesotho	0
Mauritania	0
Somalia	0
South Sudan	0
The Gambia	0

Figure 1 - Overview of African pharmaceutical manufacturing plants by country. Libya and Liberia report no production, while no data are available for Niger, hence these countries' figures are zero.
Source: Geoffrey Banda et al., *The Localisation of Medical Manufacturing in Africa*, cit. Elaboration by IAI.

The challenges

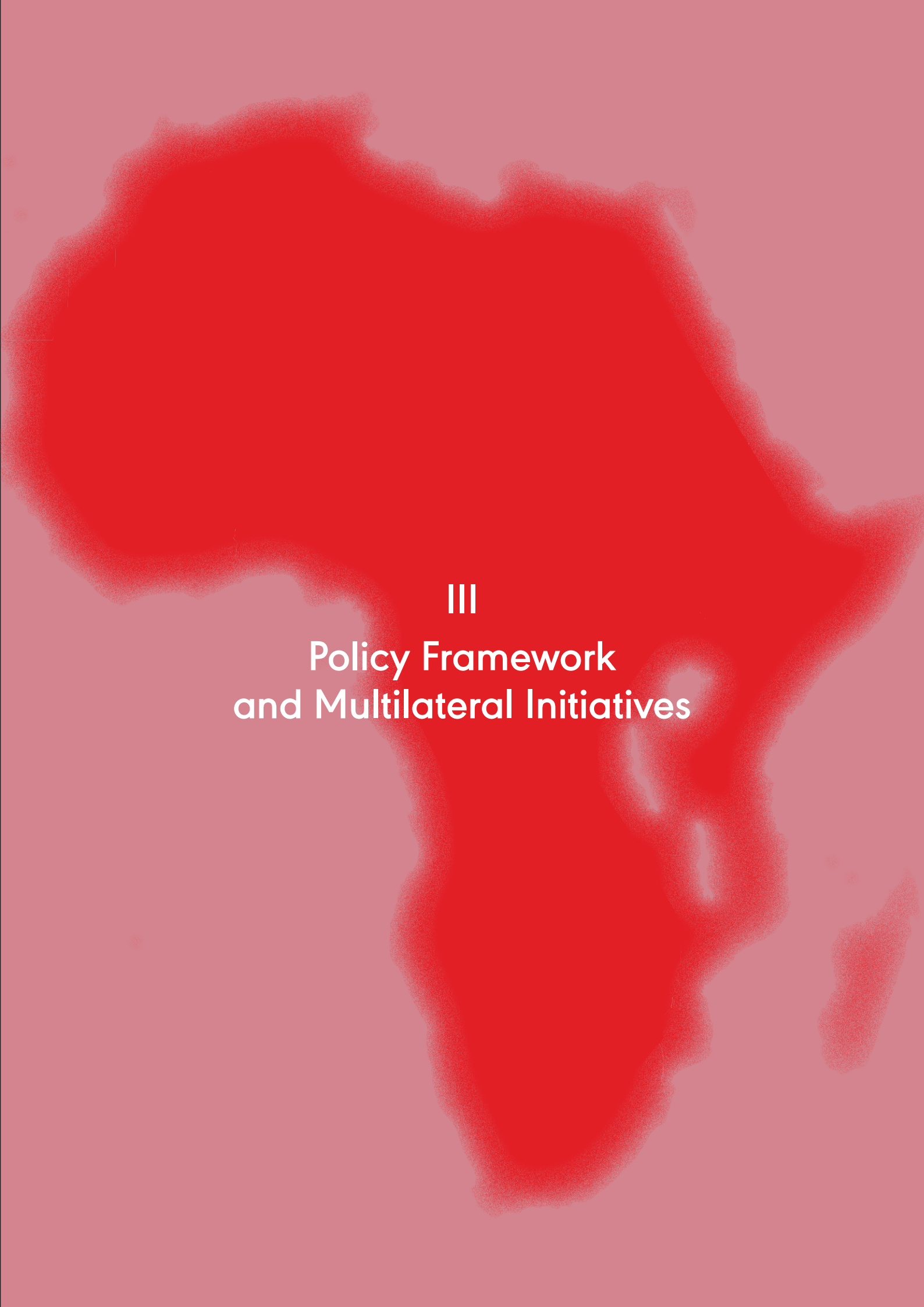
A series of supply, demand and business environment factors currently hamper the efforts to sustainably scale up health product manufacturing on the continent.

From the supply side, trade barriers affect the availability of materials, APIs and equipment to produce health products. While the African Continental Free Trade Area (AfCFTA) can help eliminate these obstacles within the continent, significant barriers remain for goods that are imported from abroad.[18] Within the continent, however, there are challenges in building a transparent and robust **supply chain** of critical raw materials and consumables, related notably to the lack of harmonised standards, regional enforcement and tracking capacity, and transport and logistical capacity.[19] In addition, the presence of **well-established, non-African competitors**, whose market power is determined by large economies of scale reached over decades and thanks to government subsidies (e.g., India and China), makes it very difficult for existing African manufacturers to expand and acquire a significant share of the market.[20] In some countries, the **market** for certain products is **highly concentrated**, making it difficult for newcomers to even attempt at competing with existing producers. This is the case in Zambia, for example, where the one-firm concentration index is 100% in the asthma, cancer, diabetes, HIV antiretrovirals and pain analgesics drug market.[21]

Furthermore, for those companies that want to start their operations, raising the necessary capital to establish an activity is difficult. Significant **capital expenditure** is required – for example, the cost of establishing a vaccine manufacturing plant is estimated between USD 60 and 130 million[22] - and **investing** in the sector is usually perceived as **high-risk**, given the presence of highly competitive actors, limited collateral and credit score of African producers, and limited market intelligence that can help make a solid business case.[23] Moreover, current rules governing **intellectual property (IP)** make technology transfer more difficult for African manufacturers, who are then disincentivised by the prospect of conducting the whole technological development process on their own, without particular support from government or private sector stakeholders.[24] Given these barriers, when pharmaceuticals are eventually introduced on the market, they have a significantly **higher price** than competitors', which makes it more difficult for manufacturers to break even and run a sustainable business.[25]

On the other hand, **demand** for local health products is either **low or fragmented**, which does not allow manufacturers to produce volumes large enough to make their operations sustainable, e.g. by producing for a whole region rather than a single country. **Limited market information** also limits manufacturers' certainty when making decisions on production volumes. Furthermore, while governments might agree to buy a specific share of health products from local manufacturers despite the higher price, this commitment might be reversed by different **political priorities** of successive administrations, different public health threats, changes in the market itself (e.g. cheaper entrants), or government budget cuts.[26] The recent case of the South African government's decision to award a tender for pneumococcal vaccines to a foreign supplier rather than a local, government-supported manufacturer[27] illustrates how national authorities' decisions are not easily predictable, which adds to an already uncertain market landscape. An additional barrier to demand of locally manufactured products might lie in the World Health Organisation (**WHO**) quality standards (**prequalification**) that health products must meet in order to be considered for procurement, especially when international bodies such as Gavi, the Vaccine Alliance are concerned. Only the Institut Pasteur de Dakar currently produces a WHO-prequalified vaccine, for example, meaning that other vaccine producers on the continent are excluded from potentially large procurement volumes, despite the proven effectiveness of their products. Given that the WHO prequalification process is lengthy, many African manufacturers decide not to undertake it. This does not imply that their medicines are of low-quality,[28] but it might exclude them from a significantly large market.

WHO prequalification issues hint at obstacles within the broader enabling environment for health product manufacturing on the continent. For **National Regulatory Authorities** (NRAs) to approve locally produced vaccines for WHO prequalification, they need to have reached a specific maturity level, independently assessed through WHO standards, which ensures they can provide proper oversight of health product development and marketing.[29] In Africa, only 3 NRAs are operating at this maturity stage (Egypt, South Africa and Nigeria), while others are working towards it.[30] Consequently, there are limited incentives to buy locally manufactured health products, since their quality is not univocally recognised. In addition, there is **low regulatory harmonisation** across the continent, which not only fosters the circulation of sub-standard health goods on the continent, further disincentivising procurers from putting large-volume orders; it also reduces the possibility of creating a regional market for locally manufactured health products, therefore fuelling low demand and disincentivising investment.[31]



III

Policy Framework and Multilateral Initiatives

WHO

The 2021 Resolution "Strengthening local production of medicines and other health technologies to improve access" (WHA74.6) provided an important political mandate for the Organisation and its member states to support local manufacturing in Africa, among other low-income regions.

Starting from the need to ensure widespread access to health products and the role that technology transfer, local production capacity building, voluntary patent pools and generic drug competition can play in this, the Assembly urged member states to show their commitment, align their national and regional strategies, develop "national and regional policies, financing mechanisms, strategies and plans of action",[32] improve the business environment, and take a holistic and coherent approach in view of strengthening local manufacturing capacity, while facilitating technology transfer too. It also tasked the Organisation to support member states' efforts in this sphere, by providing technical support, regulatory capacity building and technology transfer assistance. Interestingly, "a mechanism for collecting and disseminating local production-related market intelligence" was also encouraged "exploring",[33] as well as supporting those countries that want to make use of provisions in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) and its related Doha Declaration to access health products.

To fulfil the WHA74.6 mandate, the WHO **Local Production & Assistance (LPA) Unit** supports countries' strengthening of local production capacity and technology transfer, by assisting them in policy and strategy design, establishment of partnerships, assistance on prequalification-related aspects, regulatory capacity building, and situational analysis to inform decision-making.[34] For example, in May 2023, it co-organised a workshop on quality and sustainable local vaccine production for African regulators and manufacturers, addressing some of the enabling environment-related barriers outlined above.[35]

In addition to this specific Resolution, two policy initiatives could provide further political support to local manufacturing at WHO level, in the broader context of pandemic preparedness. The **medical countermeasures (MCMs) platform** that is currently being developed in view of future pandemics aims to ensure better coordination among stakeholders, so that everyone can access essential health products (medical countermeasures) in a fast, equal, inclusive and efficient way.[36] One of its areas of work is manufacturing, which together with research and development (R&D) and delivery is likely to be built in non-pandemic periods, so as to make the instrument effective during pandemics. While local manufacturing does not seem to be explicitly mentioned, low and middle-income countries, which faced the greatest barriers to access during Covid-19, will receive particular attention. In addition, given its planned synergies with technical agencies, such as the Africa Centres for Disease Control and Prevention (CDC),[37] it is easy to see links with discussions around local manufacturing of health products.

The proposed "WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+)", also known as the **Pandemic Treaty**, similarly aims to improve multistakeholder coordination in view of future pandemics, encompassing alert systems, information sharing, research, production and distribution of critical health products.[38] Production and technology transfer fall under the scope of the instrument, which in early versions encouraged manufacturers to share and transfer relevant technology, in view of strengthening low-income countries' productive capacities in particular.[39] To ensure the new political commitment to build better pandemic prevention, preparedness and response can be followed through, the **Financial Intermediary Fund for Pandemic Prevention, Preparedness and Response (Pandemic Fund)** was launched in 2022 to finance "critical investments" to strengthen related capacities "at national, regional, and global levels, with a focus on low- and middle-income countries".[40] Hosted by the World Bank with technical leadership by the WHO, it started operating with an initial capital of USD 1.4 billion, pledged by Australia, Canada, China, European Commission, France, Germany, India, Indonesia, Italy, Japan, South Korea, New Zealand, Norway, Singapore, South Africa, Spain, United Arab Emirates, United Kingdom, United States, Bill and Melinda Gates Foundation, Rockefeller Foundation and Wellcome Trust. By building on participating institutions' comparative advantage, the Pandemic Fund will "provide complementary support, improve coordination among partners, incentivise country investments, serve as a platform for advocacy" and keep health systems strengthening on the political agenda.[41] Grants were approved under the first call for proposals, supporting projects on disease surveillance and early warning, laboratory systems and health workforce strengthening.[42] While health product manufacturing capacity is not explicitly mentioned under the priority areas,

capacity building for MCMs is included, providing a potential avenue for financial support to African manufacturing capacity-related projects.

African Union (AU)

The African Union development agency, AUDA-NEPAD, first adopted a Pharmaceutical Manufacturing Plan for Africa (PMPA) in 2007, in order to create "a sustainable supply of quality essential medicines" to the benefit of public health and economic development.[43]

By focusing on strengthening regulatory systems and oversight, building human capital, increasing industry competition, making demand more predictable, providing affordable finance and incentives to production, PMPA aimed to "develop a competitive and enduring integrated pharmaceutical manufacturing industry in Africa" that aligns with the continent's pharmaceutical needs.[44]

In the wake of the Covid-19 pandemic, the African Union called for a **New Public Health Order**, built on five pillars. Alongside stronger public health institutions, a stronger public health workforce, increased domestic investment in health and more effective partnerships, pillar 3 focuses on "expanding local manufacturing of health products". In order to do so, actions are encouraged from three types of stakeholders:

↗ AU Member States are called to coordinate with AU institutions (Africa CDC, AfCFTA Secretariat and AU Commission) to increase demand for Africa-manufactured health products;
↗ "vaccine purchasing mechanisms", such as Gavi, are requested to procure a minimum of 30% of their vaccines from African manufacturers;
↗ international government, private sector and civil society partners are called "to remove trade and intellectual property-related barriers".[45]

Within the health product sphere, the pandemic gave particular impetus to strategies to increase vaccine manufacturing on the continent. The **Partnerships for African Vaccine Manufacturing (PAVM)** were launched in 2021 so that by 2040, 60% of the vaccines that are used for routine immunisation are manufactured on the continent.[46] The 2022 **PAVM Framework for Action (FFA)** lays out the 8 programmes designed to achieve this goal, which address the different issues in scaling up African manufacturing that were illustrated above:

1. Operationalising a continental vaccines **procurement pooling mechanism**
2. Strengthening **NRAs** as well as Regional Centres of Regulatory Excellence
3. Creating a **Vaccine Manufacturing Deal Preparation Facility**, to support companies in building sound business plans for investors and securing investment
4. Creating a Vaccine **Technology Transfer and Intellectual Property Brokering Service**
5. Establishing coordinated vaccine **R&D centres**
6. Setting up **Regional Capability and Capacity Centres** for skills development
7. Ensuring **trade policies** support vaccine manufacturing
8. Creating an **oversight mechanism** to monitor overall implementation.

The FFA sets specific targets and forecasts in these areas. For example, 22 critical vaccines are prioritised, for diseases that are a) currently widespread, such as tuberculosis and measles; b) do not have marketed and/or affordable vaccines at the moment, such as HIV and malaria; c) outbreak diseases, such as Ebola. In addition, to achieve the 60% target, 23 manufacturing plants are likely necessary, both for drug substance (DS) production and fill and finish (F&F) capacity, as well as 23 technology transfers and workforce expansion to 12,500 full-time employees. Delivering the FFA is projected to cost USD 30 billion.[47]
While PAVM was launched to build vaccine manufacturing capacity on the continent, it has now expanded to diagnostics, treatments and health products at large. Under its **2023 – 2027 Strategic Plan**, the Africa CDC included the expansion of "health product and technology innovation and manufacturing"[48] as one of its six

priorities. In the next four years, the African CDC aims to:

1. "Provide support to enable scaling up capacity and infrastructure for local manufacturing and supply chain needs";

2. "Provide support to inform the market design and demand intelligence, thus driving healthy markets for locally produced health products";

3. "Strengthen the local R&D ecosystem through facilitating intellectual property (IP) and technology transfer and increasing R&D capabilities and capacities";

4. "Attract investments to drive delivery of regional manufacturing initiatives through catalysing strategic partnerships and resources".[49]

In support of these strategic goals, other AU and non-AU institutions are currently engaged in the local manufacturing sphere. The treaty establishing the **African Medicines Agency (AMA)** is awaiting ratification by all AU Member States for the Agency to begin operating.[50] It will be critical to strengthen the regulatory environment for the production of quality health products, by setting continental standards and regulations, reviewing clinical trial applications, inspecting medical products and pharmaceutical manufacturing plants and "sharing information about products authorised for marketing".[51] From the financial side, the **African Development Bank** supports PAVM by focusing on local production capacity development, in the areas of regional logistic integration, quality industry standards implementation and R&D fostering. **Afreximbank** aims to complement these activities by providing "project preparatory support, financial advisory services, project finance and risk bearing instruments".[52]

AFRICA CDC PAVM GOAL

MANUFACTURE
60%
OF ROUTINE IMMUNISATION VACCINES ON THE AFRICAN CONTINENT BY
2040

22
critical vaccines

23
technology transfers

23
manufacturing plans

12500
full-time workforce

Expected cost
$ 30 billion

European Union (EU)

In the wake of Covid-19, the EU has included support to local health product manufacturing capacity in its new international partnerships and global health strategies.

The **EU Global Health Strategy** aims to improve global health outcomes as well as preparedness and response to global health threats. In this latter regard, the focus is on "a more equitable access to vaccines and medical treatments by strengthening local pharmaceutical systems and manufacturing capacity", alongside more stringent pandemic rules, stronger disease surveillance and a One Health approach.[53] **Global Gateway**, the blueprint for the EU's international partnerships, includes health among its priority sectors, focusing specifically on "the security of pharmaceutical supply chains and the development of local manufacturing". To this end, not only does it aim to support capacity building, but it "will also facilitate investment in infrastructure and the regulatory environment", so as to achieve market integration and foster innovation.[54]

Stronger health systems are one of the areas addressed by the 2022 **EU-Africa Global Gateway Investment Package** too, where European institutions and Member States committed to support African vaccine manufacturing in its different aspects – delivery, infrastructure, human capital, regulations and production capacity.[55] The Team Europe Initiative **Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+)** is one of Global Gateway's flagship projects in Africa. With an initial EUR 1 billion endowment, it addresses supply, demand and enabling environment-related hurdles to support PAVM's goal to produce 60% of African-needed vaccines in Africa by 2040. Financial incentives and de-risking instruments are provided to support investment in local health product

manufacturers; work is underway to consolidate African demand for African health products and to reduce market fragmentation on the continent; and EU institutions are meant to collaborate with their African counterparts to strengthen regulatory frameworks and ensure quality health products reach markets. To this end, it works regionally with AU institutions and private sector actors to foster regulatory capacity and market integration. It is also active nationally in Senegal, Rwanda, South Africa and Ghana to strengthen selected plants' manufacturing capacity and scaleup.[56]

G7

G7 countries put low and middle-income countries' (LMICs) local manufacturing capacity on the political agenda in 2022, in the context of broader discussions to enhance pandemic preparedness and response.

Under the **2022** German Presidency, leaders published a **Pact for Pandemic Preparedness**, built on the pillars of collaborative surveillance and predictable rapid response. To ensure the latter, the promotion of "R&D, regulatory capacities and manufacturing efforts" was identified as essential. On the one hand, G7 countries committed to allow pre-planned technology transfers, regulatory updates, faster delivery and "sustained manufacturing capacity" so that new vaccines, diagnostics and therapeutics could be made available more quickly during health crises. On the other hand, leaders agreed to "support options for the expansion of clinical research and manufacturing capacity in LMICs and the industry's efforts in this regard".[57] This was echoed by the **G7 Development Ministers' Meeting Communiqué**, where "sustainable, regionally diverse vaccine and essential medical product manufacturing capacity in developing countries, supported by the creation of sustainable markets", was declared to be essential to improve equity in access to health products and pandemic preparedness. Consequently, Ministers stated their willingness to contribute to strengthening local manufacturing capacity, with a particular focus on Africa, declaring their support for the AU 60% by 2040 goal and highlighting the work conducted at the mRNA manufacturing hub in South Africa (see further below). To this end, voluntary technology transfer and licensing, regulatory frameworks and sustainable markets were the factors that Ministers agreed to focus on.[58]

Under the 2023 Japanese Presidency, local manufacturing capacity took slightly less of a centre stage, but it was included in continued discussions around pandemic preparedness and response. On the future of the pandemic ACT-A, the **G7 Nagasaki Health Ministers' Communiqué** highlighted the importance of partnerships in "the development, manufacturing, procurement and delivery of MCMs for [pandemic preparedness and response]".[59] Hence, it stated G7 countries' support for an holistic MCM ecosystem built on partnerships between governments, international organisations and bodies "such as WHO, WB, UNICEF, the Global Fund, Gavi, CEPI [...] Unitaid and the Medicines Patent Pool (MPP)", regional organisations, development banks, civil society and private sector to advance innovation and R&D, voluntary licensing for health products, "geographically diverse and sustainable manufacturing" and delivery.[60] The **G7 Hiroshima Leaders' Communiqué** highlighted G7 countries' commitment to "invest in global health through vaccine manufacturing capacity worldwide",[61] as well as "the urgent need to foster innovation and to strengthen research and development of safe, effective, quality-assured and affordable medical countermeasures (MCMs) as underlined by the 100 Days Mission".[62] To this end, the **G7 Hiroshima Vision for Equitable Access to MCMs** and the **MCM Delivery Partnership for equitable access (MCDP)** were launched, built on the principles of equity, inclusivity, efficiency, affordability, quality, accountability, agility and speed.[63]

Existing initiatives in the local

	PAVM	MAV+	LPA	Pandemic Fund
Leading entity	AU	EC	WHO	WB & WHO
Type of entity	Intergovernmental	Intergovernmental	Intergovernmental	Intergovernmental
Funders (sovereign)	AU institutions & MS; EC	EU institutions & MS	WHO MS	Australia, Canada, China, EC, France, Germany, India, Indonesia, Italy, Japan, South Korea, New Zealand, Norway, Singapore, South Africa, Spain, United Arab Emirates, UK, US
Goals	Achieve 60% of local vaccine production by 2040	Support PAVM 60% by 2040 goal	Support local production capacity & technology transfer	Support pandemic prevention, preparedness and response in LMICs
Target issue	Demand certainty; enabling environment/ quality; business case preparation; technology transfer/IP; R&D; human capital; trade barriers	Financial support; demand certainty; market integration; enabling environment/quality	Enabling environment/ quality; institutional capacity building	Disease surveillance, laboratory, risk management, human capital, MCM capacity building
Scope	Vaccines, diagnostics and treatments	Vaccines, medicines and health technologies	Health products	Health systems
Diseases	Priority	N/A	N/A	N/A
Partners with**	EC, CEPI, Gavi, WHO	AU, WHO	N/A	N/A
Is this a specific initiative?	Yes, programme	Yes, TEI	No	Yes, fund
Example of specific initiatives?			Workshop for African regulators	

Figure 2 - Table summarising and comparing existing initiatives in the local manufacturing landscape.

manufacturing landscape

CEPI	AVMA	GF	mRNA Technology Transfer Hub Programme	Unitaid
	Gavi		MPP & WHO	
International organisation	International organisation	International organisation	International organisation	International organisation
Australia, Austria, Belgium, Canada, Denmark, Ethiopia, Finland, Germany, Greece, Hungary, Iceland, Indonesia, Italy, Japan, Kuwait, Lithuania, Luxembourg, Malaysia, Mexico, Netherlands, New Zealand, Norway, Panama, Philippines, Portugal, South Korea, Romania, Senegal, Serbia, Singapore, Spain, Switzerland, UK, US, Saudi Arabia, EC	N/A	Australia, Austria, Brazil, Canada, France, Italy, Japan, Norway, Spain, UK, US, EC*	AU, Belgium, Canada, EC, France, Germany, Norway, South Africa	France, UK, Norway, Brazil, Spain, South Korea, Chile
Accelerate development and deployment of vaccines against epi/pandemics	Support sustainability and upscale of local vaccine production	Ensure equitable access to quality health products to end HIV, TB, malaria	Support mRNA technology adoption and production of generic medicines in LMICs	Support development and widespread adoption of innovative health solutions in LMICs
R&D; manufacturing	Financial support; demand certainty	Demand certainty; market integration; enabling environment/regulatory harmonisation	Technology transfer/IP; human capital	R&D; technology transfer/IP; demand certainty
Vaccines and other biologic countermeasures against epidemic and pandemic threats	Vaccines only	Pharmaceuticals, diagnostics, other health products such as insecticide-treated malaria prevention nets	Vaccines and treatments	Health products
Known (priority pathogens: Lassa, MERS, Rift Valley Fever, Nipah, Chikungunya and Ebola) and unknown threats (Disease X)	N/A	HIV, TB, Malaria	Priority	Priority
AU, Gavi, WHO	CEPI	MPP, Unitaid	AU, EC, Unitaid	GF, MPP, WHO
No	Yes, financial instrument	No	Yes, programme	No
Manufacturing innovations to accelerate vaccine production		Quality assessment of Africa-manufactured HIV rapid diagnostic tests		

* for the full list of public donors, see https://www.theglobalfund.org/en/government
** only partnerships with analysed actors are mentioned here.

IV
Initiatives by Global Health International Organisations

To implement the visions set out by the intergovernmental bodies mentioned above, and to complement the initiatives they have launched to foster local health product manufacturing, a number of global health international organisations have adapted their strategies and initiated programmes to support this goal too.

CEPI

The Coalition for Epidemic Preparedness Innovations (CEPI) aims to "accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats", so that they can be widely accessible to populations in need in a short amount of time.

It currently focuses on vaccines against Lassa, MERS, Rift Valley Fever, Nipah, Chikunguya, Ebola, Covid-19, coronaviruses and Disease X, an unknown pathogen. CEPI takes an end-to-end approach and acts in two capacities, both as a funder and a facilitator, focusing on vaccine development, licensure and manufacturing, while supporting vaccine discovery, delivery and stockpiling, in partnership with industry, governments, academia, foundations, international organisations, civil society and regulators.[64]

Equitable access to vaccines is central to CEPI's activities, whose broader goal is to ensure "vaccines are first available to populations when and where they are needed [...] regardless of ability to pay". This implies not simply accelerating product development, but also securing rights to produce vaccines that are most needed in high-risk populations in the Global South, aligning investment decisions with utility for the Global South, and fostering more agile and resilient research, development and manufacturing systems. To realise this goal, CEPI engages in advocacy to make the broader health system more equitable; coordinates with partners to align investments and technologies; includes **equitable access obligations in its investment agreements**; and works only with partners that share its vision and mission.[65] In addition, when CEPI-funded vaccines are developed, it coordinates with relevant partners to enable them to be **licensed** or achieve appropriate regulatory milestones. When vaccines are licensed, it is committed to enable they can be **procured**, allocated, deployed and administered, at a **price** that is **affordable** for buyers and **sustainable** for manufacturers.[66]

To support vaccine R&D and manufacturing in Africa, since 2021 CEPI has launched different activities. In 2021, it signed a **Memorandum of Understanding with the AU/Africa CDC** to strengthen pandemic preparedness, "invest in vaccine R&D innovations", "invest in capacity building and training", support laboratories and research hubs, and "build partnerships that enable the sustainable expansion of vaccine manufacturing in Africa", while more broadly supporting and working with PAVM.[67] CEPI has funded clinical trials for vaccines against diseases that affect African populations (Ebola, Lassa Fever, MERS, COVID-19) in more than 15 countries in Africa, and is going to support clinical trial sites for a first-ever Phase 3 Lassa Fever vaccine efficacy trial in West Africa and to develop a strategy to enable long-term epidemic research preparedness in the region. Moreover, it **co-financed establishing alum vaccine fill/finish capability at Aspen** (South Africa) **broadening their scope supporting an agreement with India's Serum Institute** that allows technology transfer of four routine vaccines, in view of building Aspen's manufacturing and distribution capacity.[68] **Aspen** was also the first pharmaceutical company to join **a CEPI global network of vaccine manufacturers** that can be quickly mobilised at the onset of a disease outbreak to manufacture and supply vaccines for either clinical trials or vaccinations. Beyond building this network, CEPI aims to train partners' workforce and matching vaccine developers with manufacturers, as well as help keep facilities operational during non-pandemic times through matchmaking.[69] The **Institut Pasteur de Dakar** joined the CEPI vaccine manufacturing network in January 2023, when it signed a 3-year, USD 15 million partnership with CEPI to establish bioprocess capability, expand production capacity for routine vaccines and reserve capacity for disease outbreaks. This involves strengthening DS manufacturing capacity, establishing a bioprocessing laboratory, investing in specialist skills development and supporting the Institute's quality management system.[70] In addition, CEPI invests in **manufacturing innovations** to make manufacturing cheaper, faster and closer to outbreaks. For instance, CEPI is supporting the development of manufacturing-related innovations and technologies that can accelerate the time required to produce vaccines,[71] and to develop innovative technologies to improve vaccine thermostability.[72] Recognising trade barriers and the need for free flow of trade, CEPI also collaborated with the World Trade Organization/World Customs Organization to help launch the harmonised coding system facilitating expedited cross-border transition of critical consumables/raw materials required for vaccine manufacturing.[73]

GAVI

Gavi, the Vaccine Alliance, is a public-private partnership that helps vaccinate more than half the world's children against some of the world's deadliest diseases. Since its inception in 2000, Gavi has helped bridge the global vaccine equity gap by immunising over 1 billion children and halve child mortality in 78 lower-income countries.

By aggregating, pooling and co-financing demand for vaccines from lower-income countries, Gavi is able to encourage manufacturers to lower vaccine prices for the poorest countries in return for long-term, high-volume and predictable demand from those countries. Moreover, Gavi's supplier base has grown and diversified over two decades, rising from 5 in 2001 to 19 in 2023 (with more than half based in Africa, Asia and Latin America).[74] Gavi financially supports approximately 30% in volume and 50% in value of total African demand, and substantially more in sub-Saharan Africa.[75] With the Alliance as a whole having responsibility for procuring up to 90% of this demand, Gavi has a substantial role to play in boosting vaccine manufacturing in Africa.

In the wake of the Covid-19 pandemic, Gavi's 5.0 strategy (2021-2025) was revised to take into account the lessons learnt to be better prepared for future public health crises. This new evolution, articulated as "**Gavi 5.1**", therefore takes stock of the several local manufacturing initiatives that were introduced on the African continent, as well as the limited number of global suppliers for critical vaccines, such as rota (3 Gavi suppliers), measles-rubella (2), measles (2), cholera (2) and malaria (1).[76] This has led to broad support for expansion of African vaccine manufacturing capacity, with a new strategy approved by the Gavi Board in December 2022. It shares CEPI's perspective regarding the importance of a strong foundation of routine vaccine production capacity, as a prerequisite for surge capacity for the next pandemic. Given its two decades of experience in shaping sustainable, healthy markets dynamics for vaccines which are accessible and affordable for lower-income countries, in 2021 Gavi started exploring how best to support the AU vision of sustainably expanding vaccine manufacturing capacity across Africa by 2040, in alignment with its mission and mandate.[77] This resulted in a new **regional manufacturing strategy** launched in 2022, developed by Gavi in response to the call to action from the African Union and the G7 Development Ministers under the German Presidency. It consists of four mutually reinforcing pillars that support and align with both the Africa CDC's strategic plan and PAVM Framework for Action:

❶ Using Gavi's technical expertise to **guide investments** towards priority, underfunded vaccines, while diversifying the adopted technologies;

❷ Accommodating the assessment criteria for **products to include in Gavi's menu** so that regional diversity, supply security and higher prices are taken into account;

❸ Increasing **predictability of country demand** for Africa-manufactured vaccines;

❹ Exploring the establishment of the **African Vaccine Manufacturing Accelerator (AVMA)**, a new Advance Market Commitment (AMC) to provide early-years support to African manufacturers.[78]

The proposed "AVMA", now under consideration, would build on Gavi's successful experience with two similar instruments. The first was the **Pneumococcal AMC**, launched in 2009 with strong leadership and financial support from Italy, as well as the Bill & Melinda Gates Foundation, Canada, Norway, Russia and the United Kingdom. Through donor commitments, this innovative funding mechanism incentivised vaccine manufacturers to produce the complex Pneumococcal vaccines at a fraction of their US cost, therefore enabling widespread immunisation in low-income countries.[79] A similar model was applied to Covid-19 vaccines in 2020 with the launch of the **COVAX AMC**, a mechanism that was funded through official development assistance (ODA), private sector and philanthropic contributions, to purchase and deliver Covid-19 vaccine doses to 92 ODA-recipient countries. The AMC complemented the COVAX Facility, which aggregated demand from high-income and ODA-recipient countries so as to provide volume guarantees to vaccine manufacturers and incentivise them to produce enough doses for participating countries, therefore de-risking the investment.[80]

The AVMA proposal is designed to contribute to **two core objectives** that align both with the AU's continental plan for vaccine manufacturing, and with G7 and G20 commitments, among others:

↗ A sustainable African manufacturing base that contributes to healthy global vaccine markets;

↗ Improved African pandemic and outbreak vaccine supply resilience.

The proposed model would offer incentives to manufacturers to help **offset the higher costs of producing vaccines in Africa in the early years**, offering new facilities with a pathway to **commercial viability**. By structuring incentives, AVMA could help optimise this emerging ecosystem, for both sustainability and global market health. Without a mechanism such as AVMA, a disorderly expansion threatens global market health and may see increased prices and decreased supply security for the world's poorest. Markets are naturally unpredictable, yet modelled scenarios for the AVMA indicate a foundational requirement of up to USD 1 billion over ten years, to support a substantial and sustainable contribution towards the AU target. An adequately and immediately capitalised mechanism such as AVMA would be essential if the necessary market signals to promote and guide long-term investment decisions are to be adequately facilitated.[81]

Global Fund

The Global Fund to fight AIDS, Tuberculosis and Malaria (GF) raises funds and invests more than USD 4 billion annually in more than 120 LMICs to fight against HIV, TB, malaria and Covid-19, as well as to strengthen health systems.[82]

Similar to Gavi's role in vaccine procurement for low-income countries, the Global Fund uses its pooled procurement mechanism, wambo.org, and procurement scale to shape the market for diagnostics, treatments and essential health commodities used to respond to its three target diseases. Every year, roughly half of the Global Fund's investments – about USD 2 billion – is used to procure key health products, ensuring they are available to those who need them most.

The Global Fund uses a competitive tender process to enter into long-term agreements with suppliers. Over time, these tenders – and close work with partners – have helped to secure **more sustainable markets and more affordable prices** for essential HIV, TB and malaria health products. For example, through its competitive tenders and the work of partners, Global Fund will be able to offer tenofovir disoproxil fumarate, lamivudine and dolutegravir (TLD), a first-line HIV treatment, for under USD 45 per person per year for the first time, which is a substantial reduction from the market entry price of USD 10,000. It is also worth mentioning that in 2021, 18% of Artemetherlumefantrine (an antimalarial medicine), 10% of insecticide-treated nets and 70% of its procured essential medicines were sourced from sub-Saharan African manufacturers.[83] Equitable access to quality health products is central to the GF's **2023-2028 strategy**, falling under the objective of "maximising people-centred integrated systems for health to deliver impact, resilience and sustainability".[84] The **NextGen Market Shaping approach**, the updated version of its Market Shaping Strategy, aims to achieve equitable access not only by supporting innovation and introduction of new products at scale, but also by "[promoting] capacity building for local manufacturing"[85] and ensuring procurement and supply chains are environmentally sustainable. To this end, the GF will leverage the power of **partnerships**; leverage its over sixteen years of procurement experience to share lessons learned and best practices with **regional procurement platforms**; and advance **financing mechanisms** "to sustain and promote national procurement capacity".[86] This requires capacity building in procurement and supply chain; advocacy for stronger and harmonised regulatory frameworks; as well as "market surveillance for quality assurance and access".[87]

Partnerships to support innovation at scale include leveraging collaboration with Unitaid (see further below), alongside affected communities, civil society organisations, donors and partners in the field. An example of this approach is the GF's partnership with the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and Unitaid to accelerate the production of **Africa-manufactured HIV rapid diagnostic tests**, by inviting manufacturers to submit their product dossiers to an Expert Review Panel hosted by WHO to provide an interim risk rating which can result in procurement while the product undergoes WHO prequalification or stringently regulatory review.[88]

Focusing on capacity building for local manufacturing in particular, the GF plans to address the main obstacles to African manufacturing outlined above by:

↗ Leveraging its **tenders** to incentivise manufacturers to meet global quality standards;

↗ Supporting stronger and harmonised regional **regulatory frameworks**;

↗ Supporting capacity building for regional **procurement platforms**;

↗ Partnering with key agencies and stakeholders to **identify priority areas for collaboration**;

↗ "[Supporting] accelerated **product qualification** and **country demand forecasting**";

↗ Promoting **technology transfer** among manufacturers.[89]

Procurement and supply chain are two key aspects of the GF's commitment to building local manufacturing capacity. With regards to procurement, the **Pooled Procurement Mechanism (PPM)** helps to aggregate volumes, build price and delivery negotiation capacity, access "competitive market terms and prices" and secure quality health products. By providing access to multiple procurement channels, the online platform **wambo.org** allows to further increase market visibility and access quality and affordable health and non-health products.[90] The GF rewards "manufacturers with production sites close to demand" in its tenders, since proximity to demand is one of the evaluation criteria in the allocation of tenders.[91] This shows the importance of supply chains too in achieving equitable access to health products. The 2021 **Supply Chain Roadmap** sets out the GF's vision to strengthen supply chains that feed positively into national health systems, are resilient, are people-centric and deliver health products where patients are, distribute quality assured goods, are efficient and support health product affordability. The GF is committed to achieve these objectives through high-level advocacy, supply chain development and operational capacity building, digitalisation and analytics, innovations to provide quality health products in health systems and investments in "country-led efforts [...] towards resilience, self-reliance and sustainability".[92]

MPP

The Medicines Patent Pool (MPP) aims to increase equitable access to health products in lower- and middle-income countries by addressing the intellectual property-related aspects of the issue.

It negotiates **licenses and technology transfer agreements** with manufacturers to encourage the production of generic versions of life-saving drugs and the development of innovative solutions. It currently holds 18 agreements with patent holders for HIV, hepatitis, tuberculosis, cancer and Covid-19 treatments and technologies, with 56 (generic) manufacturers that received sublicenses so far.[93]

Per its **2023-2025 strategy**, MPP's activities are set to support both pandemic preparedness and increased local manufacturing capacity. Besides equitable access to Covid-19 countermeasures, strategic goal 4 aims to ensure that licensing and technology transfer are central to the next **pandemic preparedness framework**, for example by advocating for the "inclusion of access provisions in R&D funding agreements" so that licensing and technology transfer can happen faster.[94] Per strategic goal 5, on the other hand, "**diversified and sustainable manufacturing capacity**" is to be supported "through licensing to local and regional manufacturers", with a particular focus on mRNA technology.[95] MPP will actively promote its licensing opportunities to local manufacturers, so as to broaden the network of its manufacturers, but it will also work to make sure manufacturers qualify for MPP licenses; and once sublicensing deals are in place, it will support its partner manufacturers to acquire the necessary skills. In order to achieve its strategic goals, MPP will "promote an enabling environment for [its] licensing activities", "support the inclusion of terms for LMIC access in licensing and funding agreements for early-stage health technologies", and "build a knowledge platform on national and regulatory requirements to support in-country registration of priority health products".[96]

The **mRNA Technology Transfer Hub Programme** is the most tangible example of MPP's support for local manufacturing capacity through technology transfer and licensing. Funded by the AU, Belgium, Canada, ELMA Philanthropies, the European Commission, France, Germany, Norway, the South African Medical Research Council and South Africa for a total of USD 117 million so far,[97] and implemented in partnership with WHO, the programme supports the development of "sustainable and locally owned mRNA manufacturing capabilities in and for LMICs". It is based on a **hub-and-spoke model**. A technology transfer hub was established at Afrigen, South Africa, with the aim to provide technological development, training and technology transfer. In the meantime, 15 partner institutes and companies (the spokes) were selected in other LMICs[98] to receive training from the hub, receive its technology, and eventually produce and sell products with that technological profile.[99] While the programme was initially launched with a focus on boosting mRNA vaccine production against Covid-19, its scope has now expanded to broader applications of mRNA technology in LMICs, particularly for widespread diseases with little therapeutic solutions, such as HIV, tuberculosis, malaria, dengue fever, Ebola, Lassa fever and human papillomavirus.[100]

Unitaid

Unitaid supports innovative solutions to address LMICs' major diseases – HIV, malaria, tuberculosis, HIV co-infections, cervical cancer, hepatitis C and fever management.

In particular, it is committed to **funding innovative health solutions and bringing them to the market**, in collaboration with **partners** such as the Global Fund. Through short-term grants, it supports partners that can scale up these innovations so that they can be marketed more quickly and at a lower cost, hence making them more accessible to those in need.[101] To do so, it relies on a **partnership** approach that encompasses technical partners developing new solutions; private sector companies using their market power to lower the cost of innovations; funders lowering the cost of medicines and diagnostics through co-payments; implementing partners bringing innovations to the most affected communities; and civil society organisations raising awareness.[102]

To achieve its mission to increase equitable access to quality and affordable health products in LMICs, two of Unitaid's **strategic objectives for 2023-2027** concern the "accelerate[d] introduction and adoption of key health products" and the creation of "systemic conditions for sustainable, equitable access".[103] In this framework, not only does the agency aim to rely on **market shaping** approaches, but also to support **local manufacturing and technology transfer**. Market shaping entails negotiating lower prices with manufacturers to encourage generic production of the same good, as well as forecasting demand to increase producers' confidence in the market. To support local manufacturing, Unitaid addresses the **intellectual property** barriers that prevent products and technologies from being deployed in LMICs, either through funding to MPP or through direct licensing negotiations with manufacturers. In addition, efforts are directed towards improving the **regulatory environment** too, especially related to quality assurance procedures. With regards to the **African continent** in particular, Unitaid aims to support a series of initiatives across these three strands of work to strengthen local manufacturing capacity. In the realm of intellectual property and technology transfer, it seeks to support **product pipeline development** for major diseases and pandemic preparedness tools; "capacity optimisation for existing manufacturing facilities", such as IPD; "quality upgrade initiatives for key raw materials"; and "a first-of-its-kind Africa-based **product development partnership for APIs and formulations development**", among others. Its planned market shaping activities fall under the broader procurement and supply chain framework; one of these aims to "support the establishment of a **pooled procurement mechanism of quality assured APIs** and other important input materials". At the regulatory level, it wants to support the **quality assurance capacities** of continental, regional and national institutions assessing health products, so that locally manufactured goods meet WHO quality standards and can be eligible for procurement.[104]

V

Policy Recommendations for Italy's 2024 G7 Presidency

Background: Italy's Global Health Commitments

Global health is one of the key sectors for Italy's development cooperation activities. The Three-year Programming and Policy Planning document for 2021-2023 mentions stronger health systems, pandemic prevention and preparedness, equitable access to prevention, diagnostic and treatment services, and "research, production and equitable distribution of medicines, treatments and vaccines" among its priority initiatives.[105]

This implies supporting the improvement of health systems, training health personnel, investing in health facilities to make them better prepared for pandemics, as well as health education and awareness.

Italy has also been a strong supporter of multilateral health initiatives in the past twenty years. Since the first financing cycle, Italy contributed more than EUR 1.6 billion to the **Global Fund**, with a gradual increase in pledged contributions for the 2020-2022 cycle (EUR 161 million, +15% over the 2017-2019 period) and the 2023-2025 cycle (EUR 185 million, +15%).[106] This has made the country the Global Fund's ninth largest public donor.[107] Italy's support for **Gavi**'s immunisation efforts and leadership on its innovative finance mechanisms has also been solid since 2006. Italy was a founding member and is currently the fourth largest contributor of the International Finance Facility for Immunisation (IFFIm),[108] with a commitment of EUR 649 million between 2006-2030. In addition, it played a key role in the launch of the Pneumococcal Vaccine AMC in 2009 and was its largest donor for the successful 10-year duration of the programme, with a commitment of USD 556 million. Italy also pledged EUR 100 million in direct contributions to Gavi's strategic cycle 2016-2020 (Gavi 4.0) and the same amount for the strategic cycle 2021-2025 (Gavi 5.0). Moreover, the country provided similar strong backing for the COVAX AMC, to which it pledged close to EUR 500 million, and donated more than 66 million Covid-19 doses through the COVAX dose-sharing mechanism.[109] With regards to accelerating vaccine innovations, Italy has also supported **CEPI** from its inception, with an initial contribution of USD 12 million for 2017-2021 and USD 27.98 million for 2022-2026, funding not only vaccine development against Covid-19 but also broader R&D efforts against future epidemics.[110] While Italy does not directly fund MPP nor Unitaid, it has been involved in EU efforts to boost local manufacturing capacity in Africa, for example by contributing to the **MAV+ Team Europe Initiative**.[111]

Furthermore, under the Italian G20 Presidency in 2021, a **Joint Finance-Health Task Force** was established to support global cooperation on pandemic prevention, preparedness and response.[112] Italy also co-hosted the **Global Health Summit** in partnership with the European Commission in May 2021 to adopt an agenda to overcome the Covid-19 pandemic and develop and endorse the G20 Rome Leaders' Declaration, which reiterated the support from G20 members to all pillars of the ACT-Accelerator. Italy is therefore well placed to lead G7 countries' renewed commitments to the local manufacturing capacity agenda in Africa during its 2024 Presidency. The next section suggests five areas where the G7, under Italy's Presidency, should act to support current efforts.

Action needed

Boosting Africa's health product manufacturing capacity has received significant political attention and financial resources between 2021 and 2022, as the large number of initiatives mentioned above makes clear. Under the lead of the upcoming Italian Presidency, what should G7 countries focus on, to ensure that the African manufacturing capacity building agenda keeps being implemented?

First, **political signalling** is key. A seeming flurry of initiatives to support local manufacturing capacity in Africa were announced during the pandemic, but references to this agenda point seem scarcer today. Drafts of the so-called Pandemic Treaty do not specifically and explicitly mention local production, nor do other instruments and declarations around pandemic preparedness, such as the Pandemic Fund and 2023 G7 Communiqués. Covid-19 being no longer a pandemic might also subtract momentum from this agenda. Nevertheless, existing initiatives such as PAVM and MAV+ make a clear case for local manufacturing capacity as a resilience building tool. Consequently, G7 countries should build on their 2022 commitments and **restate their support to the local health product manufacturing objective in Africa in view of building stronger pandemic preparedness**, for example **by clearly referencing current AU-led efforts such as PAVM and existing initiatives by the above-mentioned partners**. The ultimate goal should be to contribute to a **distributed, regionally based health product manufacturing ecosystem** that can better mitigate supply disruption risks and can be highly responsive to regional capacities and needs. This commitment should not simply be limited to the G7 framework, however - it should be brought to those multilateral fora that are currently building the post-pandemic health architecture too, for example **by including a clear reference to local manufacturing capacity building in the WHO Pandemic Treaty**.

Building manufacturing capacity for vaccines, therapeutics and diagnostics across the African continent is equally important as the pandemic has exposed clear examples of unequitable access to all health products. It is therefore recommended that G7 leaders **commit to supporting the broader *health product* manufacturing agenda**. This would show mindfulness of the diversity of the manufacturing landscape on the continent, and allow local stakeholders (AU, regional economic communities, AU Member States) to make political and financial choices that align with local needs and agendas, ensuring ownership of these decisions.

Beyond political commitment, G7 countries yield significant power to affect two key barriers to local health product manufacturing capacity in Africa. One of these is the **intellectual property regime**, which currently hinders the production of health products at scale on the continent for the continent's population. Some of the initiatives outlined above are actively addressing this issue – the work conducted by MPP being crucial in this regard – but while these efforts are making a positive impact, they are relatively limited in scope. The Covid-19 pandemic brought out a structural obstacle to health equity, with the significant debate around the proposed TRIPS waiver for Covid-19 vaccines.[113] While the Pandemic Treaty under negotiation contains provisions to facilitate technology transfer to LMICs during pandemics, observers have noticed that the language is not particularly strict.[114] G7 countries could help steer the conversation back towards equity by first **pledging collective support for MPP's activities, in particular the mRNA Technology Transfer Hub Programme**; second, by **committing to a TRIPS waiver for those health products (vaccines, technologies, drugs) that are the most effective in disease burden reduction but are currently under-utilised and under-produced on the continent due to IP barriers.** To select these health products and identify a priority list, coordination with the AU and multilateral bodies working on the field, such as the Global Fund, is crucial – while ensuring that affected communities have the chance to feed into the discussions too, as well as monitor the evolution of these processes.[115] Third, G7 countries could **include access considerations in the very early stages of R&D and develop access conditions or commitments (e.g. technology transfer) in their R&D funding and procurement agreements**. Such moves would signal G7 countries' stand on IP issues and possibly steer Pandemic Treaty conversations back to equitable health access.

The second barrier to boosting local manufacturing capacity in Africa relates to **finance**. Due to the nature of the health product manufacturing market on the continent, significant financial effort needs to be made over at least ten years if manufacturing plants are to run their operations sustainably. While financial commitments have been made by AU and EU actors through their ad-hoc initiatives and in collaboration with their financial institutions, the timeline for the use of these funds is not clear.

Moreover, they are spread over a series of workstreams that support the AU's 60% by 2040 goal, but do not necessarily focus entirely on production capacity. Consequently, an **Advance Market Commitment** such as Gavi's African Vaccine Manufacturing Accelerator (AVMA) that is entirely dedicated to supporting sustainable vaccine manufacturing in Africa in the first years of operation could be a significant step towards boosting local manufacturing capacity. This represents a unique example of African private sector investment and entrepreneurialism resulting in pandemic resilience, vaccine self-reliance and a new, diverse and sustainable biotech industry. Under the leadership of the Italian Presidency, the G7 members should support such a global mechanism.

This can be complemented with financial support to **broader health product manufacturing**. With regards to the sources of such funding, specific budget lines could be envisaged for health product manufacturing capacity within existing frameworks. For example, a **specific call to this end could be launched for the allocation of the next Pandemic Fund grants**. In the longer term, based on multilateral entities policies and frameworks, the G7 countries could agree to **refer to support to health product manufacturing on the African continent when announcing increased pledges**. They could underline the need for **strengthening the coordination and complementarity** of actions among those health entities and the AU bodies, in line with transparency and ownership standards. In addition to public sources of funding, leveraging the **private sector** is crucial too. European and African financial institutions are working to **de-risk investment in local production on the continent** by facilitating contacts between investors and manufacturers and by helping manufacturers build a compelling investment case. These efforts should go beyond these two regional actors and extend to other G7 countries' development banks and institutions, as well as **global development finance institutions and multilateral development banks**.

In addition to immediate sources of funding, it is important to keep broader conversations around the international financial architecture in mind. The increasing **cost of debt** servicing has led LMICs, in particular African countries, to make tough decisions between servicing their debts or financing public goods like education and health. As long as governments are forced to prioritise debt servicing over health spending,[116] it will be very difficult to bring the health product manufacturing capacity agenda forward, even when grants and instruments to leverage private sector investment are devised – short-term gains (immunising the population at the lowest cost) will trump long-term ones (building supply chain resilience through local manufacturing capacity). To break this cycle, and to ensure that African governments have the appropriate fiscal space to make long-term investments in their health sector, G7 leaders should **support reforms of the international financial systems that allow LMIC governments to continue investing in their health security even in the case of severe financial downturns**.[117]

Policy Recommendations for Italy's 2024 G7 Presidency

Political commitment

1. State renewed support to building African health product manufacturing capacity, clearly referencing AU efforts (PAVM) and existing initiatives, in view of creating a regional production ecosystem.

2. Bring this commitment to the multilateral level too, pushing for the explicit inclusion of this objective in the text of the Pandemic Treaty.

Define the issue

3. Commit to supporting manufacturing capacity building in the African health product sector as a whole, including vaccine production.

Intellectual property

4. Pledge collective support to MPP, especially the mRNA Technology Transfer Hub Programme.

5. Agree to a TRIPS waiver on priority health products, which are to be identified in partnership with affected communities.

6. Include access considerations in R&D funding and procurement agreements.

Financial support for health product manufacturing

7. Support an AMC-like instrument with a clear, realistic timeline for boosting vaccine manufacturing in Africa.

8. Include local manufacturing capacity building in the next Pandemic Fund call for proposals.

9. Include reference to supporting African health product manufacturing capacity and increasing actor coordination when announcing pledges for CEPI, Gavi, GF, MPP and UNITAID.

10. Devise de-risking tools to foster private sector investment in African health product manufacturing in additional development finance institutions and multilateral development banks.

International financial architecture

11. Support reforms of the current sovereign debt system to avoid trade-offs between debt servicing and social welfare in LMICs.

Notes

1 UN, *WHO Chief Declares End to COVID-19 as a Global Health Emergency*, 5 May 2023, https://news.un.org/en/story/2023/05/1136367.

2 WHO website: *UN General Assembly High-Level Meetings on Health 2023*, https://www.who.int/news-room/events/detail/2023/09/20/default-calendar/un-general-assembly-high-level-meetings-on-health-2023.

3 WHO website: *Intergovernmental Negotiating Body*, 2023, https://inb.who.int. See also chapter III below.

4 European Commission DG Health website: *Health Emergency Preparedness and Response Authority*, https://commission.europa.eu/node/14025_en.

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