The EU's Global Role
Policy Proposals for a New Era

Diversifying Manufacturing of Health Products

CENTER FOR GLOBAL DEVELOPMENT

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What is the challenge?

COVID-19 laid bare the shortcomings in health product markets that contributed to inequitable access to medical countermeasures like vaccines, treatments, and diagnostics in low- and middle-income countries. A key challenge is that manufacturing for health products is concentrated in a handful of countries. COVID-19 vaccines were initially produced only in the European Union, United States, Russia, China, and India—a distribution that mirrors the limited geographic footprint of vaccine manufacturing capabilities.

This makes reliance on imported health products a reality in regions like Africa and Latin America. Currently, Africa imports 99 percent of the vaccines administered on the continent. Latin America and the Caribbean produces only 1.4 percent of the total global share of vaccines (compared, for example, to 0.2 percent in Africa).

To address these challenges, governments in these regions have made significant political commitments, supported by financial pledges from international partners, to diversify manufacturing of

SUMMARY

- COVID-19 exposed existing shortcomings in health product markets that contributed to inequitable access to medical countermeasures, such as vaccines, treatments, and diagnostics, in low- and middle-income countries. A key challenge is that manufacturing for these products is concentrated in a handful of countries.
- The European Union and its Member States have been one of the largest funders supporting governments and regional partners in Africa and Latin America to bolster production capabilities of both pandemic-related and routine health products.
- As it advances the European Union's role in the health products manufacturing ecosystem, the new European Commission should focus on the following four priority actions:
  1. Promote coherence across manufacturing initiatives via a dedicated coordinating platform;
  2. Strengthen demand for locally manufactured products by supporting regional and subregional procurement;
  3 Align funders on a continuum of manufacturing capabilities across product types; and
  4 Diversify regulatory pathways as a key enabling factor for diversified manufacturing.

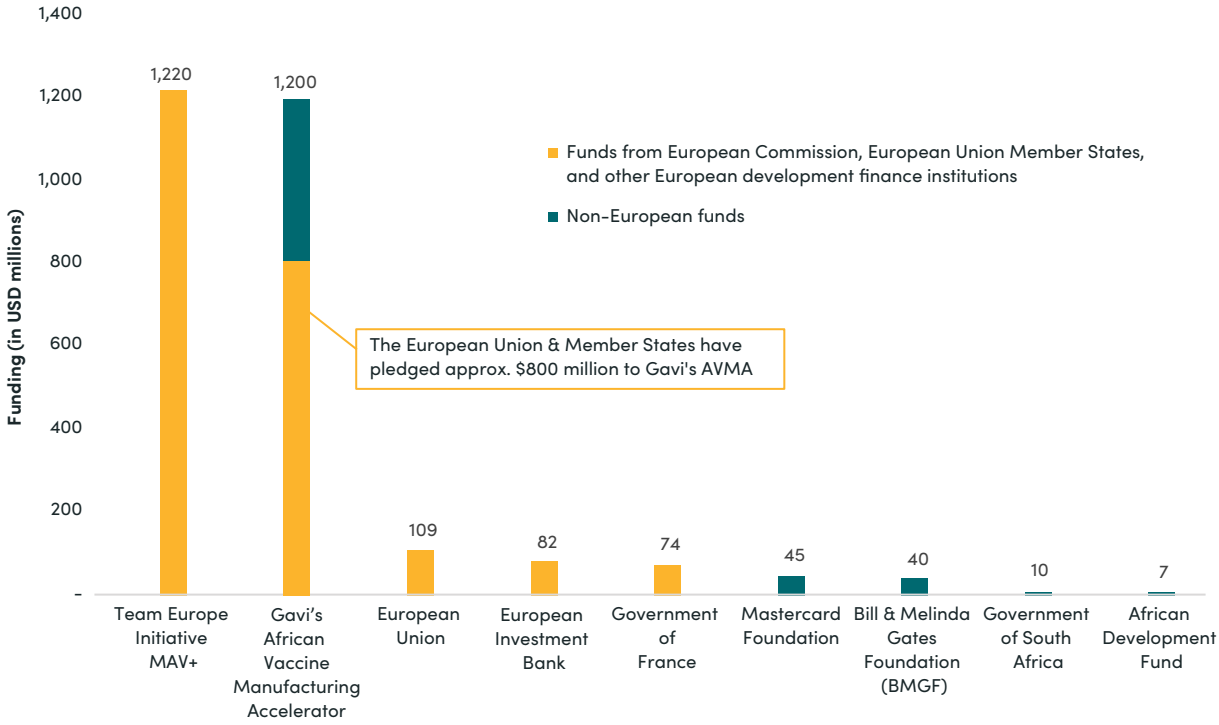
both routine and pandemic-related health products. The African Union, for example, aims to expand production of vaccines, treatments, and diagnostics, with an explicit goal to manufacture 60 percent of Africa's vaccine needs in the region by 2040. The European Union (EU) and its Member States have been a key player in the health products manufacturing ecosystem, providing significant financing and technical support to governments and regional partners in Africa and Latin America.

As efforts to diversify manufacturing advance, the European Commission should seize the opportunity to bolster European leadership in a rapidly evolving ecosystem. This brief offers a series of policy ideas for the incoming Commission to maximize the impact of the EU's investments in this space.

What is the European Commission's role and comparative advantage?

The EU has been a prominent partner in the push for diversified manufacturing, which is outlined as a key action to improve global health security in its new Global Health Strategy. The EU has been one of the largest funders in this space, contributing over US$2 billion to date (Figure 1). This includes funding through Team Europe's €1 billion Initiative on Manufacturing and Access to Vaccines, Medicines, and Health Technologies (MAV+) in Africa,[1] alongside a similar partnership focused on Latin America and the Caribbean. The EU is also an important funder to global health initiatives, especially Gavi, the Vaccine Alliance.

FIGURE 1 Financing contributions from select funders to African health products manufacturing (based on most recent data, non-exhaustive)



Notes: (1) This figure is non-exhaustive and summarizes the financial commitments made between December 2020 and October 2023 that are included in PATH's Africa R&D Commitment Tracker database (last accessed June 13, 2024; last updated May 30, 2024). (2) Gavi's recently launched African Vaccine Manufacturing Accelerator was not included in PATH's database at the time of analysis, but is included in this figure due to the relative size of the financial commitment, including more than $800 million from the European Union and its Member States. (3) $109 million from the European Union represents support for the African Medicines Agency (AMA) and other African medicines regulatory initiatives.

Led by the European Commission, MAV+ aims—at least in theory—to take a comprehensive focus on the supply side (e.g., facilitating investment in local pharmaceutical and biotech companies); demand side (e.g., consolidating demand, facilitating market integration); and the broader enabling environment for manufacturing (e.g., regulatory frameworks). But success will ultimately hinge on how these commitments are translated into practice.

To date, tangible actions on some of these fronts, most notably on the demand consolidation side (beyond contributions to Gavi), are less evident in the public domain.[2] Details on the relative intensity of Team Europe's focus on each of these areas and the degree of coherence across them, which are key determinants of success, are also unclear from publicly available sources.

What should the new Commission do?

The new European Commission should seize the opportunity to bolster its leadership at the pan-European and global levels to drive coherent investments supporting a more diversified manufacturing ecosystem. To achieve these objectives and demonstrate the value of collective action in this space, the new Commission should focus on the following four actions as it advances its role in the health products manufacturing ecosystem.

1. Promote greater coherence across manufacturing initiatives via a dedicated coordinating platform.

To achieve the full impact of current and future investments, the Commission should play a leadership role in strengthening coherence[3] across multiple dimensions of the manufacturing ecosystem. This is essential to ensure financing and policy actions are well coordinated across the demand side, supply side, and broader enabling environment for manufacturing.

First, greater alignment is needed across its own investments (including across relevant Directorate Generals within the Commission), as well as across efforts under the Team Europe banner spanning different regions (e.g., Africa and Latin America and the Caribbean) and product types (e.g., vaccines, diagnostics, treatments). This will help maximize impact across supply-side and demand-side interventions as well as actions focused on the broader enabling ecosystem, while also ensuring a more coherent approach in determining the right mix of financing modalities (e.g., loans versus grants and linkages with other sources of concessional financing).

Second, greater coherence is needed among the wide array of international partners involved in the increasingly complex health products manufacturing ecosystem. Estimates suggest there are around 25-30 vaccine producing initiatives focused in Africa alone. This underscores the need for greater coordination between international actors focused on different—but interconnected—aspects of the manufacturing ecosystem, namely the R&D pipeline, workforce availability, regulatory maturity, supply chains, demand-side factors, and an effective underlying ecosystem to ensure long-term sustainability.

A coordinating mechanism, championed by the Africa CDC alongside leadership support from the European Commission, could help fill such gaps. In the near-term, the Commission could support building on the Regional Vaccine Manufacturing Collaborative, but with an expanded scope beyond vaccines. As a first step, such a platform could enable governments, regional bodies, and external financing partners to build consensus around the vision for regionalized manufacturing for different product types. From there, it could serve as a platform to exchange key information on the overall funding landscape, including details on specific vaccine platforms and antigens being supported. It could, in turn, help drive alignment amongst these actors on the key factors needed for an enabling environment and who is leading efforts to close various gaps. Finally, it could provide

critical functions such as consolidated demand forecasting, alongside policy guidance on procurement frameworks and diversified regulatory pathways (more below).

2. Strengthen demand for locally manufactured products by supporting procurement of products that meet local needs through regional and subregional African institutions.

To help consolidate demand and obtain economies of scale for regionally manufactured health products, the Commission should focus on demand consolidation for products for which procurement is currently fragmented and insufficiently pooled. Specifically, the EU should provide financing to purchase regionally manufactured products that are (1) essential and cost-effective; (2) tailored to the needs of particular regions/sub-regions; (3) not covered/supported by other global health initiatives; (4) could be procured through regional and sub-regional procurement mechanisms, including the pooled procurement mechanism spearheaded by the Africa CDC, once operationalized; and (5) co-financed with domestic funds. This approach would help leverage the Commission's efforts to support nascent manufacturers to address gaps in health product markets that are considered fragile while also complementing—rather than duplicating—ongoing efforts by global health initiatives and international partners (including but not limited to Gavi for vaccines; the US President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund, and UNITAID for HIV/AIDs, etc.).

As a subsequent step, the Commission, as part of the coordinating mechanism described in recommendation 1, should support the development of a list of priority products for African manufacturers. For vaccines, the list could focus on novel antigens that are regionally relevant and/or antigen markets where global supply is limited, with an eye to maintaining global market health. But the list should go beyond vaccines/antigens to include diagnostics and drugs where additional product prioritization would fill important gaps.

This approach would not only help advance the viability of a nascent manufacturing industry but would bolster regional and subregional African institutions to conduct procurement of health products and, in turn, strengthen regional regulatory pathways. Over time, these institutions could have an expanded scope, encompassing a broader set of health products. This could eventually include products currently purchased by other global health initiatives and international partners, providing a pathway to transition away from reliance on external support.

3. Lead efforts to align funders on a continuum of manufacturing capabilities for a range of health products.

Alongside its demand-side focus, the European Commission should seek to align funders around what constitutes an optimum continuum of manufacturing capabilities, and the role funders can play in supporting specific aspects of this continuum. For instance, the manufacturing capabilities required to produce products like insulin and sterile products could serve as a useful steppingstone to develop more advanced capabilities to produce vaccines. Importantly, this would also reflect diversification of business models, potentially boosting commercial viability.

Such a framework could be developed under the auspices of the coordinating mechanism described in recommendation 1. Subsequently, the EU, as part of Team Europe, should align its financing and technical support with this framework—and should prioritize investments in the highest potential manufacturing projects to minimize market fragmentation and maximize the chances of success.

As one way to help provide support for bolstering drug product capacity (i.e., manufacturing antigens which is at the most capacity intensive end of such a continuum), the EU should help identify additional health products for which the intellectual property rights are held by European companies and for which there are supply gaps in lower-income

markets (e.g., amoxicillin). This could take the form of voluntary licensing agreements directly managed by industry or building from a pool (e.g., Medicines Patent Pool). Alternatively, and importantly, the EU could include incentives for technology transfer as part of efforts to revamp EU pharmaceutical legislation.

4. Diversify regulatory pathways as a key enabling factor for sustainable regional manufacturing capabilities.

Building on its ongoing efforts in this area, the EU should engage on a larger scale by supporting alternative regulatory pathways that meet international regulatory standards, diversifying beyond the WHO Prequalification pathway for regulatory approval. These alternative pathways could be leveraged to enhance regulatory capacity that informs procurement and supports regional manufacturing.

As part of these efforts, the EU should support subregional pathways which would be anchored by initiatives established within Regional Economic Communities (e.g., East African Community, Southern African Development Community), and supplemented by the six functional African National Regulatory Authorities assessed as having stable, well-functioning, and integrated regulatory systems per the WHO Global Benchmarking Tool.[4] This approach would also provide a steppingstone to the African Medicines Agency (AMA), which aims to serve as a functional, continent-wide regulatory agency.

The European regulatory network, comprised of the European Commission, the European Medicines Agency (EMA), and respective National Regulatory Authorities in Member States, provides a suitable model for African subregional initiatives. The EMA and the European National Regulatory Authorities should also fully leverage their status as WHO Listed Authorities and accept products manufactured in countries with non-functional regulatory authorities that are not intended to be marketed within the EU. Taken together, these efforts could help ensure more timely access to new health products that meet stringent international quality requirements, while also advancing diversified manufacturing and regional procurement.

Finally, for products procured with its financing, the Commission should update policies adapted to these diversified regulatory pathways. And it could also nudge the global health initiatives, such as Gavi and the Global Fund—which receive funding from the EU and its Member States—to embrace alternate regulatory pathways.

Endnotes

1 Funding for MAV+ comes from the EU budget, EU Member States (France, Germany, and Belgium), and European financing institutions including the European Investment Bank and other bilateral banks. Within the Commission, the Directorate-General for International Partnerships (DG INTPA) leads efforts focused on health product manufacturing, though other directorates may be involved as relevant.

2 Others have cited the lack of more granular information about funding allocation and project design across Team Europe's initiatives as a broader challenge.

3 We refer to coherence as alignment of financing, policies, and incentives within European partners (spanning Team Europe, Member States, and European development agencies and finance institutions) and across international partners, low- and middle-income country governments, and regional bodies that are engaged in the broader ecosystem for manufacturing of health products.

4 The six are as follows: Tanzania Medicines and Medical Devices Authority – ML3 for Medicines since 2018; Ghana Food and Drugs Authority – ML3 for Medicines since 2020; Egyptian Drug Authority – ML3 for vaccines since 2022; Nigeria's National Agency for Food and Drug Administration and Control – ML3 for Medicines since 2022; South Africa Health Products Regulatory Authority – ML3 for Vaccines since 2022; and Medicines Control Authority of Zimbabwe – ML3 for Medicines, 2024.

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This brief is part of series, The EU's Global Role: Policy Proposals for a New Era. The series will set out a suite of policy proposals designed to shape the international development agenda of the European Union's leadership during the 2024-2029 term.

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