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A partnership in progress: Africa and the EU strive for global health and equitable access

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The COVID-19 pandemic disrupted Africa-Europe relations and revealed deep inequalities in access to health services, vaccines and treatments. This compelled African and European actors to act, leading to significant political and financial commitments at the AU-EU Summit in 2022. Consequently, the development of African public health institutions and medicines regulatory authorities has accelerated. This paper reviews progress in the AU-EU health partnership and analyses its current direction, identifying converging interests and areas requiring further dialogue and alignment.

The paper shows that African and European actors have common interests and that African and European health strategies have shared objectives, notably for global health security, health supply chain diversification and health workforce development. However, financing for health systems remains a hurdle, and the issue of health technology transfer remains contentious – although joint investments by African and European actors in vaccine production capabilities during the pandemic have shown that practical solutions can be found to expand pharmaceutical manufacturing in Africa. Yet, sustainably enhancing access to medicines, vaccines, diagnostic tools and health technologies requires a system approach. Improving access also depends on the strength of community health systems and the sustainable financing of national and regional institutions and regulators.

As the pandemic threat recedes, health might move down the list of political priorities. Nevertheless, the principle of equitable access to health, the notion that health spurs sustainable economic development and the established Africa-EU health-related institutional mechanisms, are steps in the right direction towards making the health partnership more resilient and promoting African health sovereignty.

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Acronyms

Africa CDC	Africa Centre for Disease Control and Prevention
ADB	African Development Bank
AfCFTA	African Continental Free Trade Area
AHS	African Health Strategy
AMA	African Medicines Agency
AMR	Antimicrobial Resistance
AMRH	African Medicines Regulatory Harmonisation
APIs	Active pharmaceutical Ingredients
ATM	Aids, Tuberculosis, Malaria
AU	African Union
AU RDI	African Union Research Development and Innovation
AU HRISA	African Union Health Research and Innovation Strategy for Africa
AUDA-NEPAD	African Union Development Agency New Partnership for Africa's Development
AUC	African Union Commission
AVATT	Africa Vaccine Acquisition Task
AVMA	African Vaccine Manufacturing Accelerator
COVAX	COVID-19 Vaccines Global Access
COVID-19	Coronavirus Disease.
CPHIA	Conference for Public Health in Africa
DFIs	Development Finance Institutions
DG INTPA	Directorate General for International Partnerships
DG NEAR	Directorate General for Neighbourhood and Enlargement Negotiations
DG RTD	Directorate General for Research and Innovation
DG SANTE	Directorate General for Health and Food Safety
DNA	Deoxyribonucleic Acid
EAC	East African Community
EDCTP	European and Developing Countries Clinical Trials Partnership
EIB	European Investment Bank
EEAS	European External Action Service

EMA	European Medicines Agency
EU	European Union
EU GHS	European Union Global Health Strategy
EUC	European Union Commission
EUR	Euro
FDA	Food and Drugs Authority
GAVI	Global Alliance for Vaccines and Immunization
GHIs	Global Health Initiatives
HEP C	Hepatitis C
MADIBA	Manufacturing in Africa for Disease Immunisation and Building Autonomy
MAV+	Manufacturing and Access to Vaccines, Medicines and Health Technologies
MDGs	Millennium Development Goals
mRNA	Messenger Ribonucleic Acid
MoH	Ministry of Health
MS	Member States
NCDs	Non-Communicable Diseases
NDICI-GE	Neighbourhood, Development and International Cooperation Instrument-Global Europe
NPHIs	National Public Health Institute
NRAs	National Regulatory Authorities
NTDs	Neglected Tropical Diseases
ODA	Official Development Assistance
PAVM	Partnerships for African Vaccine Manufacturing
PHC	Primary Health Care
PMPA	Pharmaceutical Manufacturing Plan for Africa
PPM	Pooled Procurement Mechanism
PPPR	Pandemic prevention, preparedness and response
RCCs	Regional Coordination Centres
RCOREs	Regional Centre of Regulatory Excellence
RDTs	Rapid Diagnostic Test
R&I	Research and Innovation
RECs	Regional Economic Communities
TB	Tuberculosis
TEIs	Team Europe Initiatives
TESS	Team Europe Support Structure
TRIPS	Trade Related Aspects of Intellectual Property Rights
SDGs	Sustainable Development Goals
UHC	Universal Health Coverage
UNICEF	United Nation Children's Fund
UNIDO	United Nations Industrial Development Organization
USD	United States Dollar
WAHO	West African Health Organisation
WHO	World Health Organization

1. Introduction

Cooperation on health exists within the framework of the established partnership between the African Union (AU) and the European Union (EU). Specifically, the Africa-EU health partnership seeks to address health needs and challenges in Africa (Box 1) and aims to inter alia strengthen health systems, improve healthcare delivery, and address various health issues on the African continent, including communicable and non-communicable diseases. In turn, improved healthcare and health outcomes contribute to the labour force's productivity, and support sustainable socio-economic development in Africa. The Africa-EU health partnership is supported by a steering committee that meets twice a year, involving the AU Commission (AUC), the European Commission (EC) and their respective member states (MS).

Box 1: Overview of some of the main health related challenges in Africa

Africa suffers from a high disease burden with the prevalence of HIV/AIDS, Tuberculosis and Malaria (ATM), other communicable as well as non-communicable diseases (NCDs) and antimicrobial resistance (AMR). Some countries are also burdened by infections by neglected tropical diseases (NTDs) such as dengue and chikungunya, dracunculiasis (Guinea worm disease), schistosomiasis and trypanosomiasis (although a few medical interventions have been successful), which mostly affect impoverished communities and disproportionately affect women and children (WHO 2023). Lowering maternal and child mortality rates and ensuring sexual and reproductive health for all remain challenging, as well as strengthening routine immunisation, reaching zero- dose children and achieving vaccine equity. Inadequate attention is given to addressing mental health. To address these multiple challenges, the continent under the Abuja Declaration, has set a target of allocating 15% of public expenditure to health, but many countries struggle to meet this goal due to incompletely developed domestic revenue systems and competing priorities. As such, cooperation on health with international partners such as the EU, remains key to achieve the Sustainable Development Goal (SDG) 3 goal of UHC and 4AQ.

Source: From the authors

Ensuring equitable access is a central principle in the Africa-EU partnership on health. This is anchored in part in the understanding of health as a fundamental human right, which underscores that everyone should have access to the health products and services they need, when and where they need them, without suffering financial hardship. Closely linked to this human-rights based approach is the concept of Universal Health Coverage (UHC). UHC plays a key role in ensuring that no one is left behind when it comes to the possibility of receiving affordable, available, accessible and acceptable health products and services of assured quality (4AQ), and is fully integrated in the SDGs.

The COVID-19 pandemic exposed the fragile state, limited resilience and insufficiencies of public health systems in most African countries. These include weaknesses in emergency preparedness and response systems and capabilities, weak health infrastructures, lack of access to medicines, diagnostics, therapeutics and health equipment specific to the pandemic and more broadly the overdependence of African health systems on international

markets.[1] This translated into strong inequalities in access to quality, safe, effective and affordable health products, services and facilities between as well as within (population segments, communities and rural vs. urban divide) countries with, for example, 65.4% against 20.1% of European and African citizens respectively vaccinated by July 2022.

In this context, African leaders have expressed ambitions to establish a New Public Health Order - Africa's health security agenda, with five strategic pillars. These pillars including the fifth on respectful and action-oriented partnerships are largely reflected in EU health policies and commitments, which, after the tensions generated during the COVID-19 pandemic and the impact on the Africa-EU partnership, need to translate into concrete support and interventions.

Therefore, while health was not always a key priority of the past AU-EU Summits, the Africa-EU cooperation in the health area has been reinvigorated in the past few years and driven in the short term by the responses to the COVID-19 pandemic, with opportunities in the long term to support resilient health systems. The health sector offers an opportunity to strengthen the AU-EU partnership in a way that aligns with Africa's objectives, supporting existing African initiatives, institutions and mechanisms, and contributing to industrialisation objectives on local manufacturing to enhance the continent's health sovereignty.

This paper analyses the Africa-EU Health Partnership, with a view to identify specific areas - given the breadth of the partnership - where there is most traction on the African and European sides to progress and achieve concrete results. The paper asks the following questions:

1. What are the current health policy processes and trends in Africa and Europe?
2. How has the partnership responded to the COVID-19 pandemic and evolved since the sixth Africa-EU Summit?
3. What progress has been made in key areas of the partnership, i.e. local production and distribution, regulatory framework and research, development and innovation?
4. How can the EU and the AU consolidate the progress of the partnership and what should they focus on next, given the opportunities and obstacles they are faced with?

The following section reviews recent African and European policies that shape the opportunities and the challenges for the partnership, focusing on the extent to which African and European actors' actions and interests align and allow for cooperation. Section 3 reviews the trajectory of the partnership in global health, considering the actions taken against the commitments made at the last AU-EU Summit in 2022. Then, the paper focuses on emerging results and outstanding challenges in key sub-sectors of the partnership in relation to equitable access, namely pharmaceutical production and distribution, regulation, and research and innovation (R&I). The paper also looks at opportunities to make further progress towards achieving health objectives and fulfilling populations' needs. It concludes with an overall assessment of the partnership and provides recommendations.

[1] According to the United Nations Economic Commission for Africa (UNECA), more than 90% of Africa's pharmaceutical and medicinal needs are imported from outside the continent, causing an annual import bill of about US$ 16 billion. The import-dependency ratio of Africa rises to 99% for vaccines alone.

2. African and European health policy processes – better aligned?

Contextualising the Africa-EU Health Partnership is important as it does not happen in a vacuum. This section provides an overview of the main health policy processes at the African and European level, with a view to i) better understand the current context, needs and priorities of the continents; and ii) draw potential implications for the Africa-EU health partnerships further presented in Section 3.

Key insights

- Broadening and changing African (and European) priorities show some key shifts such as notions of health sovereignty and health security to enhance self-reliance and reduce vulnerability to supply disruptions.
- There is broad alignment of priorities between EU and Africa where commitments need to be translated into actual interventions to remain credible e.g on supporting local production, R&I and regulatory frameworks.
- Both partners share a common interest and belief in the multilateral system - yet not necessarily driven by the same interests and/or approaches- resulting in different positioning at global health fora.
- Health will remain a key issue within the partnership. For Africa, it's about addressing health needs and some of the main market and regulatory/policy gaps, while for Europe, it is about how they can support this agenda whilst also supporting their own interests whether linked to development, geopolitics or economic considerations - given the importance of the pharmaceutical industry.

2.1. African policy priorities

The Africa Health Strategy (AHS) (2016-2030) provides guidance for public health policies at the AU level, building on pre-existing political commitments, strategies and policy documents (including inter alia the Continental Policy Framework For Sexual and Reproductive Health and Rights, its Maputo Plan of Action for the period 2016-2030, the African Regional Nutrition Strategy 2015 – 2025, and the Pharmaceutical Manufacturing Plan for Africa). While continental strategies may have limited influence and impacts, the assessment of the previous 2007-2015 Africa health strategy suggests that political commitments taken at the continental level have had a positive influence on the effectiveness of health policies of AU MS and regional economic communities (RECs). That is the case in particular for the reduction in HIV-related mortality, through prevention and treatment, and in maternal and child mortality (AUC 2016). The current AHS aims at:

1. Achieving UHC through the strengthening of health systems and improvements in the social determinants of health in Africa, in accordance with the Agenda 2063 and the SDG 3; and

2. Reducing morbidity and ending preventable mortality from communicable and non-communicable diseases and other health conditions in Africa.

The first strategic objective, anchored in the principle of health equity and in a human rights-based approach, is of prime importance in a context where 48% of African countries' populations (over 600 million people) lack access to essential services while the quality of care is often low, which contributes to large numbers of deaths from commonly preventable diseases (Adebowale-Tambe 2023). Achieving this objective requires adequate resources, which has become increasingly challenging given the current limited fiscal space and sovereign debt vulnerability of many Africa countries. In practice, only a few AU MS allocate 15% or more of their annual budgets to the health sector (a target set out in the Abuja Declaration of 2001) (AUDA-NEPAD 2019a).

Increasing health financing through innovative and sustainable funding mechanisms is recognised as a key issue. To address it, AUDA-NEPAD launched its Health Research and Innovation Strategy for Africa (HRISA): 2018-2030 (AUDA-NEPAD 2019b), in line with the Africa Health Strategy (2016-2030) (AU 2016), recognising the importance of investment in R&I for tackling the challenges that the African continent is grappled with. Added to this, the African Development Bank developed its own Strategy for Quality Health Infrastructure in Africa - 2022-2030, which aims to support the access to quality health services for the people of Africa by 2030. This shows that the health governance architecture is not necessarily centralised, with each African institution approaching health from their own perspective - even though the Africa Centres for Disease Control and Prevention (Africa CDC), with its new status providing it with greater autonomy, has gained further importance in this context.

When it comes to health spending, a large share of public health expenditures goes to the top of the pyramid of health systems, that is, hospitals in major urban centres, serving affluent populations. Health organisations at the bottom of the pyramid, at the district level, such as dispensaries receive comparatively fewer resources. This is a key issue given that the health district model contributes to expanding the coverage of essential services in efficient and equitable ways by ensuring the access to and availability of primary healthcare (PHC), workers and health products, including for vulnerable populations (Harmonization for Health in Africa 2013).

The issue of resources has also an impact on African research innovation (R&I) ambition. Building on the AHS which dedicates particular attention to R&I, HRISA signals an intent to invest more resources into R&I as a way of improving access to health products and medical technologies. However, the situation analysis of the HRISA highlights several factors hindering innovation in African countries, including small public research budgets, poorly developed mechanisms for financing R&I, as well as weak intellectual property management.

Building on the lessons of the 2007-2015 African health strategy, the current AHS as well as the New Public Health Order and the Africa CDC have put a specific focus on strengthening African health institutions and systems, especially at the community level. Currently the national health systems of most African countries are inadequately staffed, with an average of 1.55

health workers (physicians, nurses and midwives) per 1000 people, well below the WHO threshold of 4.45 health workers per 1000 people required to deliver essential health services and achieve UHC (Ahmat et al. 2022). Besides the shortage of labour, it is also about a shortage of skills: the uneven availability and competencies of health workers across local communities constitute a major obstacle to improved healthcare services delivery for all. This issue is particularly acute in rural areas and poor communities where an informal private healthcare sector of considerable size has developed, filling a gap left by the formal healthcare delivery system (Kumah 2022).

In the wake of the pandemic, in 2022, the call by the AUC and the Africa CDC to all stakeholders to support the implementation of Africa's New Public Health Order emphasised the goal of Africa's health sovereignty, contributing to health security in Africa and globally. Its five pillars are: i) strong Africa public health institutions that represent African priorities; ii) expanded manufacturing of vaccines, diagnostics and therapeutics; iii) investments in public health workforce and leadership programmes; iv) increased domestic investment in health and v) respectful action-oriented partnership. To bolster this, the Africa CDC at the 3rd Conference for Public Health in Africa (CPHIA) in November 2023, outlined its vision to reshape the African healthcare landscape through an emphasis on 5Cs: Community, Connectivity, Capacity, Collaboration, and Climate (Box 2).

Box 2: Overview of the Africa CDC vision: 5Cs

The 5C approach focuses on strengthening the resilience of communities by addressing the gap of community health workers, critical in ensuring access to health services. To this end, the Africa CDC will support an increase of two million paid community health workers by 2030. Connectivity relates to leveraging the digital innovations to enhance the continent's ability to detect emerging health threats. The 5C approach also focuses on strengthening the capacity of the skilled health workforce and Africa's medical manufacturing capabilities to enhance self-reliance and reduce vulnerability to supply disruptions. Collaboration stresses pooling expertise and working collectively to safeguard and enhance population health. Lastly, the Africa CDC, is committed to addressing the linkage between climate change and health in Africa by adopting a comprehensive One Health approach to tackle climate-related challenges.

Source: From the authors

With this new health agenda, additional priorities - often part of complementary strategies[2] - came along for the AUC and the Africa CDC, including supply security for health product commodities. This requires the localisation of production of priority vaccines, therapeutics and diagnostics (one of the focuses of the Pharmaceutical Manufacturing Plan for Africa) as well as strengthening regulatory capacity. Improving the supply of locally produced vaccines would also help sustain and scale immunisation programmes in Africa, as planned in the AHS. In 2021, 12.7 million children were under-vaccinated, including 8.7 million who did not receive a single dose, also called "zero-dose" children (UNICEF 2023).

More recently, the second Africa CDC strategic plan (2023-2027) identifies five programmatic priorities - most of which follows those of the AHS and Africa's New Public Health Order. In

[2] See Annex 1 for a non-exhaustive list of African health-related strategies and policies.

addition to strengthening health systems and emergency preparedness and response capabilities as well as fostering the R&I capabilities and infrastructure, it puts further emphasis on the Africa CDC Non-Communicable Diseases (NCDs), Injuries Prevention and Control and Mental Health Promotion Strategy (2022-26). This is partly explained by the burden of NCDs in sub-Saharan Africa, which grew by 67% between 1990 and 2017 and is higher than the global average (Africa CDC 2022). Mental health conditions, cardiovascular diseases and neoplasia are responsible for most of the rise in the burden of diseases due to NCDs. In fact, the first-ever African Union Task Force on NCDs, Injuries, and Mental Health was launched in November 2023.

Africa's health needs are therefore vast, encompassing the need to address ATM, NCDs, AMR and NTDs as well as diarrheal diseases, respiratory diseases other than TB, perinatal morbidity[3], high maternal and child death rates and mental health. COVID-19 exacerbated existing health challenges and highlighted the fragility of national health systems. At the continental level, current priorities identified were influenced in part by the COVID-19 pandemic and its impact on health value chains, which led to a stronger focus being placed on the notion of health sovereignty, as a means to ensure the access, availability and affordability of health products in the continent.

2.2. European policy priorities

In 2022, the EC adopted a new EU Global Health Strategy (GHS), which was approved by the Council of the European Union in its January 2024 Conclusions, confirming the EU and its MS' commitment to global health (EU 2022). The GHS aims to:

1. Deliver better health and well-being of people across the life course;
2. Strengthen health systems and promote UHC;
3. Prevent and combat health threats, including pandemics, applying a One Health approach.

While the EU GHS is a global strategy, it will influence and has been influenced by the EU's partnership with Africa in health. Aside from addressing Africa's health needs and challenges, investments in health can open avenues for improved collaboration on research and development of health technologies and medical products, clinical trials or other domains of mutual interest and foster interdependencies from a public/global health perspective within the partnership. Cooperation between the EU and AU therefore provides a pathway to strengthen the diplomatic and economic ties between the continents.

The GHS actually integrates commitments made at the AU-EU Summit, including to support '*regional and country efforts to strengthen pharmaceutical systems and manufacturing capacity for vaccines and other medical products and technologies to increase quality, safety, equitable access, and health sovereignty*'. Furthermore, its scope encompasses various elements of Africa's New Public Health Order, including the notion of health sovereignty, the primordial role of PHC and the importance of building capabilities for public health, while relying on the principles of access to essential health services and products as a human right, equal partnerships and shared responsibilities.

[3] Associated sepsis for neonates and mothers are amongst the leading causes of death in some African countries.

Box 3: Examples of alignment of objectives between the GHS and Africa's New Public Health Order

This alignment in terms of priorities is partly reflected in the programming aspects including the TEIs (for example, MAV+, Africa-based public health capacity and others). During and right after the COVID-19 pandemic, the EU focused on local manufacturing of vaccines, access to medicines, and pandemic preparedness, with the purpose of improving health security (reflecting the second objective of Africa's New Public Health Order).[4] Likewise, the regional TEI focusing on Africa-based public health capacity echoes the first objective of Africa's New Public Health Order whilst the GHS/MAV+ aim to address workforce imbalances and improve skills reflecting the third priority of Africa's Public Health Order.

Source: From the authors

The shortage of labour and skills - partly driven by the "brain drain" (felt strongly during the pandemic) is a major bottleneck for local manufacturers and foreign direct investors. The inclusion of education and training amongst the objectives of the Global Gateway's investment package for Africa but also in the GHS may present an opportunity to boost support for scientific and technical education and training for the health sector, in cooperation with African actors and the WHO. Importantly, the GHS has additional objectives as reflected by some of its regional health related TEIs, which should enable progress in the areas of inter alia SRHR and sustainable health security as well as digital health.

The GHS will be supported by the Global Gateway health investment package, which adds a geopolitical layer to European external action. In this context, there could be tensions between the EU's geopolitical and geo-economic interests – pursued through the Global Gateway – and its interests in supporting African initiatives and tackling health inequalities. More generally, the component of the Global Gateway directed to Africa has been criticised by some observers for its lack of transparency and consultation with African partners before the Summit - although the Joint Vision for 2030 document contains several health commitments. Furthermore, although health is supposedly one of the priorities under the Global Gateway, the focus of flagship initiatives in Africa has been largely on infrastructure, with only a few flagship projects focusing on health. While it is still early to assess the actions undertaken under this strategy in cooperation with Africa, the GHS runs the risk of losing traction/interest as political attention is moving away from the COVID-19 pandemic - even though European actors have an interest in cooperating with African countries in the health sector to contribute to equity, economic growth, and global health security.

Beyond the GHS, the EC issued in 2023 a communication on 'Addressing medicine shortages in the EU' and a process was launched to revise the general pharmaceutical legislation, on the back of concerns about import dependencies during the pandemic (Tondel and Ahairwe 2020). Previously, in late 2020, the Pharmaceutical Strategy for Europe the period 2021-2025 was adopted as part of the EU health policy to support R&I in the EU pharmaceutical industry and improve the regulatory framework. Reflecting the focus of European policies on health security and strategic autonomy, European companies have since been incentivised to diversify their supply chains for health inputs.

[4] Interview with EC official, September 2023.

All in all, the GHS seems to be a framework conducive for an Africa-EU cooperation to tackle major African public health challenges. Though broader in scope, the GHS is relevant to, and builds on Africa's endeavour and, if implemented well through the TEIs and other measures, could lead to concrete development impact and a renewed trust in the Africa-EU health partnership. At the same time, mirroring the health security focus of Africa, Europe is also developing strategies aiming to secure the supply of health products, which could translate into potential opportunities in Africa (if value chains diversified away from China and to a lesser extent India), although they could also have negative spillover effects onto low- and middle-income countries.

2.3. Interests in the global health architecture

The AU and EU share a common objective of actively engaging in multilateral fora to address global health challenges. Considering the shortcomings of the multilateral system and the problems of coordination during the COVID-19 pandemic, political leaders have been concerned with strengthening global health security and governance. That is why the AU and the EU stated their intent to work together for the elaboration of a new World Health Organization (WHO) multilateral agreement on pandemic prevention, preparedness and response (PPPR), namely the Pandemic Accord. The latter aims to: i) create a legally binding obligation to report public health emergencies and allow for faster verification and investigation of potential threats to public health; and ii) establish mechanisms to ensure actions following the declaration of a public health emergency of international concern. Alongside the Pandemic Accord, additional approaches and multilateral mechanisms are being discussed including the Medical Countermeasures Platform/Medical Countermeasures Platform for future health emergencies, to ensure equitable access to vaccines, diagnostics and therapeutics during pandemics and major epidemics (which builds on the Access to COVID-19 Tools Accelerator (ACT-A) and the COVAX Facility) (Nikogosian 2023).

Yet, the development of the accord has been met with resistance and strong oppositions between different actors. Disagreements over the modalities of reporting of public health emergencies, pathogen information sharing, and responses (tests, treatments and vaccination) have been the objects of heated debates and also reportedly misinformation (regarding, for example, health security) and unfounded arguments (The Guardian 2024). While African and European countries have a common interest in ensuring that pandemics and infectious diseases are monitored, contained and controlled, some contentious points have also emerged.[5] While European countries expect that more resources should be invested in epidemiological surveillance, information sharing and access to healthcare services, African countries want first greater access to technology and international financing (including debt reduction or restructuring), in addition to adequate access to the pandemic 'countermeasures'.

[5] Global health has emerged as a geopolitical issue over the past few decades, in part due to the growing cross-border interconnections in the context of globalisation, economic interests, and the threat of diseases destabilising states (Ingram 2005). For example, in Germany, pandemic prevention and response is part of the new National Security Strategy adopted in 2023.

Another challenge African and European actors at the multilateral level is more broadly to promote a renewed focus on health system strengthening and UHC and implement political commitments for the latter. Indeed, while several Global Health Initiatives (GHIs) (such as GAVI, the Global Fund to Fight AIDS, Tuberculosis and Malaria, UNICEF et cetera.) were born/strengthened throughout the past two decades, they have adopted a vertical type of approach. In turn, this has created siloes and has, as an unintended effect, created high levels of dependencies on international partners. This undermines the development of local health systems, by creating parallel health systems and attracting scarce human resources. In addition, some diseases (including NDCs and chronic diseases, PHC, and mental health) have not benefited from the same interest and financing as some of the GHIs (Holst and Razum 2022).

The international response to the COVID-19 pandemic has to some extent followed a siloed approach and a lack of focus on health system strengthening, driven by concerns about global health security and focused on supply-side solutions. In response to this situation, two UN General Assembly high-level meetings on health—on PPPR and on UHC— that took place in September 2023 led to the adoption of high-level political statements addressing the perceived imbalance between health security and health system strengthening (Nikogosian, 2023). In addition, the recent increase in contributions of MS to the WHO, coupled with the planned replenishment rounds in 2024 and the additional provision of core funding by high-income countries, could boost WHO capacity to support the strengthening of (African) national health systems, health ministries and national regulatory agencies (with the assistance of the WHO Africa Office in particular).

Overall, Africa and the EU consider the multilateral fora, including the WHO, as a relevant place to engage in further discussions related to global health. This does not necessarily mean that the two continents always have common positions and interests, as illustrated in the case of their positions in the negotiations of the Pandemic Accord, which is now on hold, as countries failed to reach consensus by the deadline, ahead of this year's 77th World Health Assembly in May 2024. This can be expected given the complexity of the topics and the sensitivity on both sides on the notion of health security and sovereignty. However, there is a convergence of interests in pushing forward a few issues including health system strengthening and the needed increase of supply for health products.

3. Responsiveness of the Africa-EU partnership in global health

In the pre-COVID period, the EU supported efforts to combat ATM, reduce child mortality and maternal deaths in Africa through various channels (EC 2018). Yet despite past successes in supporting global health, European and African actors did not always sustain the political momentum in this domain, and progress on UHC stalled and in some cases reversed. Within the EU, funding for health competes with other priorities such as green and digital, reinforcing the need to keep political and financial momentum. Within Africa, health challenges have persisted owing to the declining funding for PHC (on average less than 5% of the GDP (Donfouet et al. 2023) and low investments in building robust and resilient health systems. These systems

were ill equipped to address the emergence of pandemics and epidemics, pointing to the need for investment in prevention, preparedness and response (PPR), including workforce capacitation to deal with such emergencies. With the onset of the COVID-19 pandemic, a succession of global political reactions and emergency policy responses that disadvantaged Africa in its equitable access to vaccines, created tensions between European and African actors.

Key insights

- The partnership has focused on both addressing short and long-term joint priorities, by mitigating the impacts of the pandemic, by supporting access to COVID-19 vaccines, and building at the same time strong and resilient health systems by supporting pandemic preparedness, health sovereignty and equitable access to quality essential health services.
- Moving from commitments to concrete interventions- a key pillar (action-oriented partnership) of Africa's New Public Health Order- is critical to rebuild trust within the partnership, and for the EU to position itself as a key partner for Africa in the health sector.
- The EU has been actively supporting health, building on joint priorities within the partnership, and African strategies (such as the PAVM) and institutions (Africa CDC, AMA) to deliver concrete interventions on the ground. These cover most of the commitments made during the 2022 Summit, and demonstrate the ambition to do more and better.
- However, some areas have received less political traction (such as prevention) and achieving consensus is hard in others (such as intellectual property rights).
- Nevertheless, the EU has been responsive to the health needs of the Africa continent providing an opportunity to strengthen the AU-EU partnerships in a way that aligns with Africa's objectives, and uses existing African initiatives, institutions and mechanisms.

At the 2022 EU-AU Summit in A Joint Vision for 2023, AU and EU leaders committed to working together to ensure fair and equitable access to vaccines in the short term, and for pandemic preparedness, health security and equitable access to essential health products and services in the mid- and long-term - all of which are seen as key elements to support African health sovereignty and capacities to respond to public health emergencies. This section looks at some of the responses within the partnership on i) the provision of vaccines; ii) the local production of vaccines and the technology transfer and iii) intellectual property rights, and (iv) how Europeans increasingly try to work with and through African institutions.

3.1. Provision of vaccines

In immediate response to the pandemic, developed countries including some EU MS, rushed to secure doses for their populations. Accusations of vaccine hoarding had a direct effect in the AU-EU partnership affecting trust and questioning the solidarity by the EU towards the global pandemic. Nevertheless, it also provided space for frank discussions around equitable distribution and spurred commitments by the EU and its MS towards vaccine sharing.

These included announcements such as the provision of in-kind and financial donations for vaccination in Africa, including 450 million vaccine doses for the Africa Vaccine Acquisition Task Team (AVATT) platform by mid-2022. In practice, 206.5 million doses were delivered by the EU to the AVATT by October 2022, while funds to purchase an additional 200 million doses were redirected towards supporting health systems strengthening and workforce training - which was also identified as a barrier to vaccines' deployment (AEF 2023). Supporting AVATT showed the EU's willingness to build on and work through African initiatives to ensure equitable access to vaccines. This effort was complemented by Team Europe's provision of over EUR 3 billion (equivalent to 400 million vaccine doses) for the COVAX Facility, through which low-income countries, including those in Africa, were able to receive doses of the vaccine.

Though commendable, lessons from vaccine sharing exposed limitations in reaching the last mile, including issues around timely delivery and the absorption of the donated vaccines. Short shelf life, limited storage facilities, poor logistical and healthcare infrastructure were among the main reasons that hampered vaccination in Africa (Guarascio and Mcallister 2022). This resulted in wastage of vaccine doses with some African countries having to destroy expired batches, and in low vaccination rates. Future modes of support need to also cater for support to ancillary mechanisms such as for complex storage, logistics and distribution methods to ensure access to health products and services. To this end, along with commitments to vaccine donations, the EU at the 2022 Summit, committed EUR 425 million and mobilised EUR 475 million for other facilities and activities for the procurement, distribution and administration of vaccine doses, training of medical teams and support for analysis and sequencing (AEF 2023).

Addressing vaccine hesitancy is also an important component that must be factored in for future support to increase rates of acceptance and uptake among communities. Reduced trust in authorities, as well as the proliferation of misinformation and conspiracy theories on social media, influenced public perceptions of vaccines. At the 2022 Summit, Team Europe committed to the fight against health-related disinformation. This provides an opportunity to collaborate under the EU Action Plan on Disinformation as well as support the Africa Infodemic Response Alliance, both aimed at combating dis/misinformation. EU partners can collaborate with national governments and local CSOs in both urban and rural areas to address this challenge. The use of digital technologies is essential in fighting social media misinformation in both public and private platforms.

3.2. Cooperation for the supply of locally produced vaccines

The African pharmaceutical manufacturing industry is distinguished by its small scale and concentration of production in a few nations, and focuses only on specific steps of the value chains (in other words, it is not vertically integrated with limited activity on research and development, and on innovation). From a regulatory perspective, National Medicines Regulatory Authorities have limited capacity to perform core regulatory functions and only a few have a stable, well-functioning and integrated regulatory system of maturity level 3, which is necessary to perform all the critical regulatory functions of marketing authorisation, pharmacovigilance, post-market surveillance, quality control, and clinical trials oversight.

Europe, in contrast, is a leading region in the medicinal and pharmaceutical sectors and amongst the largest traders in these products. It has large pharmaceutical companies, which make a considerable contribution to the economy, and advanced research institutes and hospitals, which provide an enabling environment for the development of clinical and therapeutic innovations for life-threatening, rare diseases.

Owing to the challenges faced by African countries in vaccine acquisition during the pandemic and ambitions to ensure African health security and sovereignty, political and financial focus has been towards the manufacturing of COVID-19 vaccines. At present, only a few African countries are able to manufacture vaccines, including Algeria, Egypt, Morocco, Tunisia, Nigeria, Senegal, Ethiopia and South Africa, with a handful of other countries planning to establish production facilities. Furthermore, due to several constraints (Saied et al. 2022), the manufacturing of vaccines in Africa consists essentially in fill-finish operations, the last stage of the process, whereas the production of antigens is very low (Karaki and Ahairwe 2022). Localising vaccine production can help African countries respond better to the needs of their communities, provide more options to consumers, diversify the market, and shorten several parts of the supply chains (USP 2023).

To address this issue, the Partnership for Vaccine Manufacturing PAVM[6] (which was preceded by the Pharmaceutical Manufacturing Plan for Africa – PMPA), was set up under the Africa CDC in 2021 (AU and Africa CDC 2022), with the aim of strengthening the continent's vaccine manufacturing capabilities and of producing at least 60% of the vaccine needs by 2040 (Annex 2). Investments in vaccine manufacturing and regulatory frameworks in Africa have thus received most visibility and support, notably with the Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (MAV+) (Box 4). At the regional level, Team Europe's support has been directed in part towards regional initiatives and bodies, especially the PAVM Framework for Action and the Africa Medicines Agency (AMA). These collaborations, without being indicative of outcomes, show that African and European actors have coordinated and followed through their commitments at the operational level.

Box 4: High-level overview of MAV+ and its main objectives

MAV+, an initiative involving the EC, some MS, development cooperation agencies and development finance institutions, is largely aligned with the objectives of the PAVM. It emphasises the need to collaborate with African partners to enhance their pharmaceutical infrastructure and manufacturing capabilities. In particular, MAV+ operates along three pillars:
1. The supply side, to incentivise and de-risks investments in local pharmaceutical and biotech companies;
2. The demand side, to reduce the fragmentation of local markets, consolidate the demand, facilitate market integration, and promote the use of locally produced goods;
3. The enabling environment, to address the threat of substandard and falsified products and boost confidence in local goods by strengthening regulatory frameworks.

Source: From the authors

[6] PAVM is now renamed as the Platform for Harmonized African Health Products Manufacturing (PHAHM).

African and European actors have invested considerable resources to establish vaccine productive capabilities and adequate regulatory framework on the African continent. The African Development Bank (AfDB) and Afreximbank have sought to financially support PAVM programmes through the implementation of a flagship programme, which is in line with its 2030 Vision for the Development of Africa's Pharmaceutical Industry (AfDB 2023). By July 2022, the EU, EU MS and their development finance institutions (the EIB European and public development banks) planned to invest EUR 1.2 billion and had already jointly provided more than EUR 906,55 million to support vaccine manufacturing in several countries, in the rough proportions of 70% of loans and 30% of grants, budget support and blended finance.

In October 2023, the Africa CDC and the EC signed an agreement to support the creation of sustainable production systems and equitable access to vaccines, medicines and health technologies in six African countries as part of MAV+ with additional financing. The pilot countries of the TEI are: namely Senegal (25 million), Ghana (32 million), Rwanda (40 million), and South Africa (16 million), plus Egypt (3 million) and Nigeria (18 million). Some of these countries also benefit from hosting the mRNA vaccine technology transfer hubs, namely Senegal, South Africa and Nigeria, which may enhance the chances of success of MAV+ and show coordination with multilateral efforts.

Although the PAVM Framework and TEI MAV+ share similar objectives, it is not always clear whether European and African partners share the same views and approach. In particular, the issue of vaccine technology transfer and intellectual property features more prominently in PAVM than it does in the framework of MAV+ – technology transfer is mentioned in MAV+ documents but in a rather *ad hoc* way, for instance as part of the operations of the WHO mRNA technology transfer hub programme. This may be linked to the reluctance of the EU to engage further on the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver, and the fact that technology transfer depends at least in part on European private sector interest.

Importantly, the Summit Declaration mentions a specific health investment package as part of the Global Gateway strategy, although not mention specific amounts. In 2023, three regional flagship projects fall under the health priority in Africa: Team Europe Support Structure (TESS) for MAV+, Digital Health, and Sexual and Reproductive Health and Rights in Sub-Saharan Africa, in addition to MAV+ TEIs in four partner countries. In 2024, seven flagship projects are expected to be implemented in the health sector in Africa, most of which fall within the umbrella of the three regional flagship projects mentioned above. In line with supporting private sector engagement in development, an EU-Africa pharmaceutical and healthcare marketplace was organised by the EC to facilitate African and European private sector (and more broadly investors, research institutes et cetera.) interactions with a view to stimulate the African health industrial ecosystem.

3.3. Cooperation on technology transfer and intellectual property rights

Access to pharmaceutical and medical technologies has been a sticking point in the relations between the Global North and Global South actors. At the 2022 Summit, the AU and the EU committed to voluntary technology transfers and to also engage constructively towards an agreement on a comprehensive response of the WTO to the pandemic. Contention within the partnership ensues over the waiver of intellectual property rights for manufacturing COVID-19 vaccines with diverging views from the partners. Though the EU broadly supports expanding production of COVID-19 vaccines, it also supports the use of compulsory licensing within the WTO's TRIPS Agreement to facilitate the expansion of production (Peseckyte 2021), rather than a patent waiver. African countries generally support the use of the patent waiver for COVID-19 vaccines. The June 2022 WTO Ministerial decision on the TRIPS Agreement gives members greater scope to take direct action to diversify the production of COVID-19 vaccines and to override the exclusive effect of patents through a targeted waiver over five years (from the decision). Furthermore, African countries supported a proposal for the waiver to be extended to cover diagnostics and treatments yet the position of the EU on this matter at the WTO Council has been more ambiguous (Holmgaard Mersh 2023). Similar divergences have occurred in the negotiations of the Pandemic Accord, where some large actors of the pharmaceutical industry have been opposing the inclusion of intellectual property waivers in the text, specifically, time-bound waivers of intellectual property rights for the manufacturing of pandemic-related products during pandemics (Lei Ravelo 2023).[7] They have argued that doing so would discourage R&I to prepare for and respond to future pandemics.

While the ability and incentives of the EU to change the intellectual property regime are limited,[8] the bloc can intervene in several ways to encourage and accelerate the transfer of technologies that are critical for fulfilling unmet healthcare needs in Africa. The establishment of productive capabilities for COVID-19 vaccines in some African countries has shown relevant innovations in terms of public-private cooperation and technology transfer.

Positive examples of technology transfer include WHO-sponsored COVID-19 mRNA vaccine technology transfer hubs in low- and middle-income countries, which together with COVAX partners, were able to create an original and effective vaccine with an immunogenic response similar to that of the Moderna vaccine[9], the first time with a South African consortium comprising Biovac, Afrigen Biologics and Vaccines, a network of universities and the Africa CDC. Team Europe, including the EC, Belgium, France, Germany and the EIB, supported the initiative in South Africa by funding the Medicines Patent Pool and the WHO and providing a

[7] At the time of writing, the text asks patent holders to waive or reduce royalty payments by developing country manufacturers for limited time periods, especially in cases where patent holders have received public funding in the development of pandemic-related products. It also asks governments to disclose publicly funded purchase agreements. However, the text does not contain any compliance mechanism.

[8] Pfizer and Moderna were particularly reluctant to share their technologies, although the research and development efforts that led to the vaccines were in large part funded by governments (for example, BioNTech had received a EUR 1 bn grant from the German government) and despite the Solidarity Call to Action led by Costa Rica and the WHO.

[9] Although Moderna announced it waived its patent, in South Africa it had not filed for patent.

EUR 15 million grant agreement to Biovac, to expand its existing vaccine production facility. This facilitated an overall investment of EUR 175 million also backed by the South African government and international financial institutions.

Another useful example is provided by the medical device and pharmaceutical industries that have met the needs of the rising middle class in Asia, notably in China and India, Latin America, and emerging African countries. Domestic manufacturing has only been partially meeting this ever-rising demand for medical services and medicines while the rest has been complemented by the participation of the multinational pharmaceutical companies, whose focus on investment in East Asia and ASEAN nations has been part of long-term market access strategies. Thus, the challenge for African and European policymakers is also to leverage the commercial interests of large companies in favour of long-term investments in R&I, production and logistics so as to address unmet needs in African countries.

3.4. Working with and through African institutions

Beyond the commitments expressed in the Summit, Africa has been vocal in ensuring that donors' interventions, including those of the EU, should build on African processes and institutions, to have a lasting and sustainable impact. Africa-EU health cooperation extends to working with and supporting the development of African health institutions, especially the Africa CDC and AMA.

Africa CDC[10] aims to strengthen public health systems and enhance the capacities to respond to disease threats and outbreaks across the continent. Since 2022, it has operated as an autonomous body of the AU Union[11] and is charged with overseeing the PAVM (with support from TESS). Yet, it remains largely financially dependent on donors, questioning the sustainable funding of its programmes. Its budget allocation for 2024 is US$ 44,872,298 representing 7% of the total AU budget, with 28,922,036 of this amount coming from support by international partners (AU 2023). This shows the over-reliance on donor funding for its programmes and points to the need for increased self-financing by AU MS to the Africa CDC. Efforts have been made to secure funding through the Africa Public Health Foundation, which works to mobilise resources for Africa CDC's funding priorities.

Between 2020 and 2022, the Africa CDC received support from a Team Europe initiative for the response to COVID-19. Additionally, over the period 2021-2024, the European Centre for Disease Prevention and Control (ECDC) and the Africa CDC collaborated to build the latter's capacity through the ECDC4AfricaCDC project, a materialisation of EU commitment to expand its collaboration in health and to address sustainable health security preparedness for outbreaks. The EU, through its TEI on Public Health Capacity, aims to strengthen public health institutions (PHIs) to jointly develop research, training, policy advice and advocacy at the regional level. Under the Global Gateway investment package on health, EUR 1.15 billion from the EU budget

[10] The Africa CDC is to work in tandem with five Regional Coordination Centres (RCCs) to coordinate regional public health initiatives but their operationalisation has been delayed.

[11] In Assembly/AU/Dec. 835(XXXV), confirmed by the Executive Council in July 2022 in EX.CL/Dec.1169(XLI).

(to be enhanced by further funding from Team Europe) is geared at strengthening health systems and pandemic preparedness with focus countries including Senegal, Burundi, DRC and South Sudan) (EU 2023).

Despite successes in support for institutional capacitation of Africa CDC and NPHIs on PPR, concerns are that the approach has focussed more on preparedness and response where governments tend to focus on improving their responses to disease outbreaks, rather than reducing the risk of their occurring in the first place (Early 2021). Preventing virus spill-overs necessitates addressing multiple sectors including human, animal and planetary health. Both the Africa CDC in its One Health Programme and the EU GHS prioritise combatting current and future health threats. As such, jointly addressing the increases in zoonoses and food-, water- and vector-borne diseases is important from a One Health approach to avoid pathogen spillovers and to control infectious diseases.

The AMA, a specialised agency of the AU, was instituted in 2019 and is headquartered in Rwanda. It is charged with improving equitable access to quality, safe and effective medical products in Africa. AMA plays a key role in evaluating medical products for the treatment of priority diseases as determined by the AU. It will also regularly inspect, coordinate and share information about products that are authorised for marketing. The EU through EMA is supporting the operationalisation of AMA, a welcome move towards strengthening the African regulatory network. This cooperation is discussed in detail in Section 5.

Overall the investments and institutional developments that have taken place in the wake of the pandemic - regarding the provision of vaccines, support to local manufacturing, cooperation on technology transfer and strengthening of public health institutions show positive signs of the potential improvement in access to essential medicinal and pharmaceutical products in Africa as well as incremental steps towards African health sovereignty - even though some challenges are yet to be overcome. Nevertheless, the early accusations of vaccine hoarding and Africa's inequitable access to vaccines have to some extent affected the trust within the partnership, pointing to the need for more frank discussions on how to make the partnership more effective and responsive towards enhancing the continent's health sovereignty. The following Sections 4-6 focus on three areas within the partnership concerning in particular access to medicines: local production and distribution; regulation and research and innovation, identifying emerging results, challenges and opportunities to strengthen collaboration.

4. Local production and distribution

Key insights

- Progress has been made in local manufacturing under PAVM, with support by MAV+, with production envisioned to extend to other prevalent diseases on the African continent. These flexible capabilities will contribute to the sustainability of investments in local manufacturing in Africa. Beyond vaccines, the manufacturing of diagnostics is a critical area that needs more investment.
- Yet to remain viable, growth in the vaccine industry should also be accompanied by growth in supporting industries to provide raw materials and inputs as well as in storage, quality control and distribution, and marketing.
- Public procurement plays a key role in building and consolidating the demand for vaccines. Incentivising countries to procure locally manufactured vaccines from the African continent poses challenges. However, opportunities lie in using the PPM (once operationalised) to leverage economies of scale in procurement.

4.1. Emerging results: investment projects for vaccine manufacturing

4.1.1. Vaccine manufacturing

Progress has been made in countries targeted by MAV+ in the framework of PAVM towards establishing vaccine manufacturing plants in cooperation with private sector actors, with financial and technical assistance from the EU, MS and European development agencies and banks. Box 5 illustrates some developments in local production in selected countries.

Although these investments were initially made to produce COVID-19 vaccines, the capabilities developed can also serve to produce vaccines for other diseases prevalent on the continent such as tuberculosis and malaria. These flexible capabilities will contribute to the sustainability of investments in vaccine manufacturing in Africa. In terms of financing, support under MAV+ incorporates not only EU funding as well as from DFIs anchoring the support as moving beyond the prism of development cooperation towards investments in health.

Box 5: Developments in local production in selected countries

- Senegal: The Institut Pasteur de Dakar (IPD) of Senegal received a loan of EUR 75 million from the EIB in June 2022 to finance the Institute's new vaccine manufacturing facility, the Manufacturing in Africa for Disease Immunisation and Building Autonomy (MADIBA) project. MADIBA is a good example of a project conceived and implemented in partnership with the private sector, in this case, Unizima, a company affiliated with the Univercells group based in Belgium. The IPD also received coordinated financial support from EU MS, including the German Federal Ministry for Economic Cooperation and Development (BMZ), which provided a 20 million euro grant through the KfW, and France, via the French Development Agency (AFD), which provided two grants for a total of 1.8 million euros (also with the support of Proparco). The MADIBA project is foreseen to have a production capacity of 300 million vaccines per year, which will supply Senegal and other African countries.

- Rwanda: In Rwanda, the German biotechnology company BioNTech built a scalable and flexible BioNTainer-based manufacturing facility for end-to-end mRNA vaccine production (for the Pfizer-BioNTech COVID-19 vaccine and BioNTech's investigative malaria and tuberculosis vaccines). The EC and the Government of Rwanda signed a €40 million financial agreement to strengthen the health product manufacturing system. At the same time, as part of an integrated approach in Rwanda, European partners have supported the medicines regulator and the establishment of MSc and PhD programmes to train the workforce in biotechnologies.

- Ghana: In March 2023, the EIB signed a 5 million grant agreement with DEK Vaccines Limited, a private sector-led consortium of Ghanaian pharmaceutical companies. The construction of the facility was launched in April 2023 and contributes to the objectives of the government's Vaccine Development and Manufacturing Presidential Committee, which oversees a 10-year strategy for developing the country's vaccine and manufacturing capacity, starting with the establishment of a fill-finish plant, followed by the expansion of capabilities for full-scale vaccine manufacturing. The facility will use imported components to assemble and package COVID-19 mRNA vaccines and supply them in West Africa. It will also be able to make malaria vaccines. Eventually, the facility will have an annual capacity of 100 million vaccine doses.

- South Africa: Support given from both European actors and the WHO directed towards scaling up the production capacity of COVID-19 vaccines. The South African firm Afrigen Biologics & Vaccines was selected by the WHO and the Medicines Patent Pool in 2021 for the piloting of the world's first mRNA vaccine technology transfer hub. This initiative was mainly supported by Team Europe. Additionally, in March 2022, Belgium contributed 3.9 million euros as part of EUR 8 million in funding to the WHO. The mRNA vaccine hub was officially launched in April 2023, focusing on R&I for the mRNA technology, besides the production of COVID-19 vaccines and other diseases such as malaria and HIV/AIDS. In 2022, the EC and the EIB set out to support expansion plans for the Biovac manufacturing facility to lift vaccine manufacturing in South Africa up to 500 million doses and they provided a grant of R281 million (EUR 15 million) in February 2023. In July 2023, a financing agreement was concluded between South Africa's Department of Science Innovation and Germany's KfW provided a EUR 20 million grant to finance the equipment for development, production, and certification of active pharmaceutical ingredients used in vaccine production in South Africa. In South Africa, the presence of both a strong R&I system and well-established private-sector actors was a key factor in the successful development of an mRNA vaccine.

Source: From the authors

4.2. Public procurement

The operationalisation of a continental vaccine procurement pooling mechanism is one of the pillars of the PAVM Framework of Action. Achieving sustainable and reliable volumes to reach economies of scale is a critical enabler to expanding African vaccine manufacturing. Public procurement at the national, regional and international levels plays a key role in building and consolidating the demand, especially for vaccines that are traditionally bought by governments rather than the private sector (Karaki and Ahairwe 2022). In addition, beyond consolidating markets, support for public procurement can help countries develop procurement strategies and manage procurement processes, which can result in a balance between supply diversification and concentration (to obtain economies of scale) in a way that increases health security (AU and Africa CDC 2022).

In 2022, AU leaders decided to establish a joint procurement mechanism for public health products through the African Vaccine Acquisition Trust (AVAT), the Africa CDC, and the Common African Pooled Procurement Systems for public health products, including vaccines. Subsequently in 2023, AU Ministers of Health discussed an initial proposal for a Legal Instrument for the adoption of the AU Pooled Procurement Mechanism (PPM), with a view to making health product manufacturing in the region viable (AU and Africa CDC 2023). In the interim, a Framework Agreement for pooled procurement of vaccines, medicines, and other health products is to be prepared by the Africa CDC to facilitate the pilot pooled procurement mechanism for vaccines while awaiting a legal instrument. The draft legal instrument was tabled for approval at the AU Heads of State Summit in February 2024, signalling an intent to use the weight of African institutional buyers to leverage economies of scale in procurement, stock management and distribution, negotiate better prices on the international markets, and source from local producers. Realising this ambition requires the establishment of information systems (leveraging digital solutions), evidence-based policies, appropriate legal and regulatory frameworks, infrastructure (such as sub-regional depots), and the mobilisation of considerable resources.

At the global level, at the end of 2023, the Board of Gavi, the Vaccine Alliance (with strong Team Europe support), approved the creation of the African Vaccine Manufacturing Accelerator (AVMA) an innovative financing mechanism, to provide early-years support to African manufacturers, comprising up to US$1 billion available over ten years to support vaccine manufacturing on the continent (GAVI 2023).[12] The facility's support will be predominantly directed towards vaccines whose drug substance is manufactured in Africa, with initial consideration also given for 'fill-and-finish only' projects using imported drug substances.[13] Its official launch will be in June 2024 during a ceremony in France. GAVI, as one of the largest purchasers of vaccines in the world, could play a role in enabling the PPM through its regional manufacturing strategy and AVMA. The EU's support for AVMA is a good example of political support for AU's ambitions beyond mere financing, to help shape market demand, which is a key component for the success of vaccine manufacturing in Africa.

4.3. Challenges and opportunities

Concerning vaccine manufacturing, PAVM's target is to produce 60% of the total vaccine doses required on the continent by 2040, though laudable risks being over-ambitious, unless accompanied by measures to overcome some of the production constraints. Currently, only a few drug manufacturers in African countries possess the capability of manufacturing vaccines beyond the fill-and-finish process. These limited capacities range from limited technology capabilities and investments in research and innovation, constrained human resources, and finances, to national regulatory agencies with low levels of maturity. Growth in the vaccine industry should also be accompanied by growth in supporting industries to provide raw

[12] AVMA works by offering two types of incentive payments that offset some of the initial high costs of production: 1) 'milestone payments' are calibrated to provide the greatest incentive to invest in modes of manufacturing most likely to support pandemic preparedness, while; 2) an 'accelerator payment', will be paid as a per-dose 'top-up', in addition to the offered market rate manufacturers receive on winning Gavi-UNICEF tenders (GAVI 2023).

[13] See: https://www.gavi.org/news/media-room/initiatives-african-vaccine-manufacturing-approved-gavi-board

materials and inputs, including active ingredients, inactive ingredients (acids and concentrates) as well as consumables (vials, sterile bottles, syringes) (AU and Africa CDC 2022). More so, local production, without concomitant investments into other areas such as storage (for example, cold chain), quality control and distribution and marketing networks risks the viability of the sector. Some investments have been made in manufacturing active pharmaceutical ingredients (APIs) as seen in the financing deal of EUR 20 million by Germany's KfW Development Bank to South Africa to develop, produce and certify APIs for vaccines (Republic of South Africa 2023). Also, the EIB announced plans to partner with the African Pharmaceutical Technology Foundation's regional biosimilars program for the production and innovation of relevant biosimilars in Africa and to facilitate the creation of common API parks (Willis 2023).

Secondly, as African countries invest in meeting the targets of the PAVM framework, the focus should move beyond vaccines towards the manufacturing of diagnostics (and therapeutics). Local production of diagnostic tools plays an important role in the effective treatment of these diseases, thus reducing the vulnerabilities in the functioning of health systems (Ndlovu 2024). It has the added benefit of making diagnostic tools available locally and fostering distribution more equitably by increasing accessibility to rural communities (Brehm 2023). Recent outbreaks of Ebola, Marburg, M-pox and Cholera within Africa, emphasise the urgency of strengthening diagnostic capacity, to bolster the continent's self-sustaining ability to detect early and respond to such threats. The manufacturing of Rapid Diagnostic Tests (RDTs) for diseases such as Malaria and HIV, COVID-19 and TB has been recorded as making positive progress within the African continent (Romano et al. 2022).[14] Yet within Africa, diagnostic programs are still largely dominated by external sponsors and partners and are often not aligned with government priorities and local contexts (Mfuh et al. 2023). Strengthening the manufacturing capacity for diagnostics requires investments and leveraging technological innovation, including the use of digital diagnostic tools. At the continental level, to accelerate access to diagnostics, the Africa CDC in partnership with key partners have launched the Africa Collaborative Initiative to Advance Diagnostics (AFCAD) to promote local manufacturing of diagnostics; map, identify and build capacity of diagnostic centres of excellence (the Africa Biobanking Network). This provides the opportunity for the TEI MAV+ to support these existing African efforts on diagnostic manufacturing.

Despite progress supporting vaccine manufacturing, coordination challenges with the EU and its MS and, between African countries within the health partnership, risk slowing down developments in local production. Within the Team Europe approach, hurdles relate to the length of time taken on decision-making, as well as challenges in optimising the use of resources and avoiding the often-observed fragmentation of interventions/priorities when they are developed individually by MS (Karaki and Ahairwe 2022). More so, as MAV+ incorporates MS development agencies and development finance institutions (DFIs), implementation requires synergies among these various actors. Coordination between African actors in PAVM and MAV+ should ensure ownership and leadership by AU MS in the implementation of interventions targeting the pharmaceutical sector. Lastly, coordination in

[14] Other international partners are supporting diagnostic production in Africa, for example, The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and Unitaid are partnering to accelerate the manufacturing of health products in Africa, with HIV rapid diagnostic tests (RDTs) as the initial focused product category.

support of production facilities is a critical factor in determining the impact and sustainability of interventions under MAV+ with other border industrialisation and regional value chain objectives under the African Continental Free Trade Area (AfCFTA), which has also identified pharmaceutical manufacturing as one of the key sectors for continental development.

When it comes to procurement, incentivising countries to procure locally manufactured vaccines from the African continent poses challenges related to competition between national procurement systems and regional ones (such as the envisaged PPM) as well as the balance between costs, if prices are higher for locally sourced vaccines versus importing affordable vaccines from outside of Africa. Some lessons can be learnt from the case of Aspen Pharmacare Holdings in South Africa, which (with political support from European leaders) was licensed to make and market the Johnson and Johnson vaccine. Aspen was unable to penetrate the regional or global market as international purchasers such as GAVI failed to make sufficient orders for the Aspenovax vaccine. So far, records indicate a possibility of Aspen's halt in the production of COVID-19 vaccines.[15] Thus, the effectiveness of efforts directed towards local vaccine production depends on the effectiveness of a commensurate demand. Given that the EU accounts for a significant share of funding of some GHIs, they could use their position to encourage the procurement agencies they support to provide indicative commitments of vaccines and other pharmaceuticals they intend to procure in the next three to five years. This would help African manufacturers build their business case based on the market dynamics; and use their grants to consider the use of paying a premium for locally produced vaccines and pharmaceutical products as part of the GHIs in order to help local production become competitive.

5. Regulation

Key insights

- Africa needs significant regulatory upgrading to enable the development of competitive pharmaceutical and biomedical industries, attract investments and supply quality and safe products.
- The AMRH has contributed to regulatory strengthening and harmonisation, in cooperation with European actors (including via MAV+ in connection with investments in vaccine manufacturing), which has led to efficiency gains and built regulatory expertise; MAV+ has helped targeted countries move up the ladder of regulatory competencies.
- Yet, regulatory harmonisation both at the continental and sub-regional levels is not always a priority; and so cooperation between Europe and Africa needs to better take into account the politics of medicines regulation.
- A future-proof regulation agenda needs to tackle illicit pharmaceutical trade as well as environmental issues.

[15] This resulted in the loss of investments as Aspen had received a joint financial package of EUR 60 million from European DFIs including the IFC, Proparco, DEG and the U.S. International Development Finance Corporation in June 2021. BIO's investment was also part of the financing package.

5.1. Emerging results: development of African regulatory capabilities

Developing the supply of, and attracting investments in, locally-produced pharmaceuticals in Africa requires effective regulatory authorities that can ensure the production and timely distribution of quality, safe, efficacious and affordable medicines, vaccines and other health products (Ndomondo-Sigonda et al. 2017). Yet, only 7% of the 55 AU MS' national regulatory authorities (NRAs) have moderately developed capacity and more than 90% have minimal to no capacity (Ndomondo-Sigonda et al. 2017). So far, in sub-Saharan Africa, only five national regulators (namely, Ghana, Kenya, Nigeria, South Africa and Tanzania) have reached the maturity level 3, on the WHO's scale of 4[16], and yet, except for South Africa, none of them is functional for the regulation of vaccine manufacturing. Currently, none of the African NRAs has attained the level 4 and can undertake the full range of regulatory functions (Ndomondo-Sigonda et al. 2017). In other countries, regulatory systems are very weak or even non-existent. These disparate levels of development in regulatory systems also hinder regional trade in medicines.

The African Medicines Regulatory Harmonization (AMRH) programme, set up in 2009, aimed at supporting NRAs and promoting the harmonisation of pharmaceutical regulatory systems across the continent (norms, standards, processes for the approval, registration and oversight of medicines, etc.), starting with the registration of generic medicines. By supporting policy and legal frameworks, regulatory capacity development and information management systems, and conducting regulatory harmonisation projects at sub-regional level, the AMRH made progress, including reduced registration times and stronger regulatory expertise, and the development of the AU Model Law[17] (Ndomondo-Sigonda et al. 2018).

Building on this, the African Medicines Agency will promote and coordinate regulatory harmonisation initiatives, unify regulatory frameworks and support mutual recognition of regulatory decisions across the continent, and support the development of regulatory competencies and capacities in African countries, especially for locally-produced medicines. In turn, this is expected to consolidate African markets and make them more attractive for investors in the pharmaceutical industry. It will also help reduce the cost of regulation (especially through regulatory reliance), thus improving the availability and accessibility of health products in African countries (Pincombe and Guzman 2022). The AMA treaty came into effect in November 2021, with (only) 26 AU MS ratifying, while an additional nine other countries have signed it. As of December 2023, the hiring of staff had yet to begin.

European actors have provided significant support to this regulatory framework. In February 2022, the EU, with some EU MS (including Belgium, France and Germany) and the Bill and Melinda Gates Foundation, announced that they collectively mobilised more than EUR 100

[16] The notion of "maturity level" is part of the Global Benchmarking Tool (GBT) used by WHO to evaluate regulatory systems. The GBT assesses a regulatory system's maturity on a scale of 1, when some elements are in place, to 4, when the system operates at an advanced level and continuously improves (see WHO 2023).

[17] The AU Model Law on Medical Products Regulation (AU Model Law for short) promoted by the AUDA-NEPAD as part of the AMRH and adopted by the AU in 2016 was intended to provide a common legal ground for regulatory harmonisation.

million to support the AMA as well as other African regulatory initiatives at the sub-regional and national levels over the following five years. In late 2022, the European Medicines Agency (EMA) pledged to provide the AMRH steering committee with technical support in the form of scientific collaboration, joint inspections and training, with resources from the NDICI-GE (Ahedor 2022). The involvement of the EMA in supporting the AMA signals the interest of the EU in not only financing but also sharing its experience, knowledge and expertise and jointly helping African national regulatory authorities achieve the minimum WHO requirements for an effective regulatory oversight of vaccine production (EIB 2023). The EC recently approved a multi-annual, collaborative programme between EMA and AMA with a EUR 10 million budget, starting in 2024. This programme will provide technical and financial support for a pilot activity for the regulation of medicines at the continental and regional levels, establishing scientific committees and involving the European network of regulators. This activity will initially focus on the EAC and SADC.

Furthermore, the European support to African medicines regulation is broader than the cooperation with AMA. The EMA has contributed to medicines regulation in African countries through other pathways. According to the EU-Medicines for all or 'EU-M4all' procedure, in cooperation with the WHO and non-EU NRAs, the EMA can assess and provide scientific opinions on medicines and vaccines for use outside of the EU, especially essential medicines for low- and middle-income countries that can prevent or treat diseases constituting major public health threats.[18] So far, the majority of regulatory approvals granted in this way have concerned African countries, with a positive effect on access to medicines (Cavaller Bellaubi et al. 2020). Another modality of regulatory cooperation is the WHO Collaborative Registration Procedure using Stringent Regulatory Authorities' medicines evaluations (SRA CRP), where EMA acts as a stringent regulatory authority. The SRA CRP procedure is based on the concept of reliance as it allows NRAs in countries with scarce regulatory resources to use scientific assessments from SRAs to approve or not health products in their jurisdiction. This procedure has been shown to have positive impacts on the efficiency and timeliness of regulatory systems and on access to medicines, including in African countries (Vaz et al. 2022).[19]

Under the regulatory workstream of MAV+, the EC has committed more than EUR 50 million for supporting African regulatory systems, including 20 million as part of its regional action. This action in the area of regulation at the regional level builds on a previous regional action for which a EUR 5 million grant was provided to AUDA-NEPAD for the AMRH and the roadmap for the establishment of the AMA.[20] At the country level, EU delegations have provided funds to the NRAs in Ghana and Rwanda (9,8 million euros were made available to the Rwandese

[18] Following its assessment, the EMA publishes its scientific opinion weighing the benefits against the risks of the product in question, with the intent of facilitating its prequalification by WHO, registration in the target countries, and possibly procurement by international agencies. This procedure combines EMA's scientific review capabilities with the local epidemiological and medical expertise of WHO and national regulators in the target countries, using the same standards as for medicines made available in Europe.

[19] Similarly, during the COVID-19 pandemic, the emergency use listing procedure of the WHO for the most used vaccines relied on the scientific reviews and approvals of the EMA.

[20] The EC has also supported regulatory strengthening in Africa through the WHO with a EUR 11,5 m contribution. The WHO mRNA vaccine technology transfer hubs have supported regulatory frameworks in developing countries participating in the decentralisation of vaccine and medicine manufacturing.

medicines regulator). The EU, the Belgian cooperation, and the Rwandan authorities have also set up a two million euro twinning operation between the Rwanda Food and Drugs Authority (FDA) and a consortium of European experts and regulators coordinated by Expertise France. The Rwandan authorities are developing a new pharmaceutical legislation that includes the principle of reliance so as to ease the marketing authorisation of medicines. Discussions are taking place to launch similar operations in Senegal, South Africa, Nigeria, Zambia, Botswana, Kenya and Egypt.

5.2. Challenges and opportunities

Technical and financial constraints hamper regulatory upgrading and harmonisation across African countries. In particular, harmonisation is difficult due to regulatory knowledge gaps and disparities and a shortage of a competent regulatory workforce (Ncube et al. 2021). It is also hampered by differences in legal systems amongst African countries, in part due to the legacy of colonial regimes. In addition, the AU does not have legal powers overriding national jurisdictions and thus its regulatory decisions are not legally enforceable in AU MS. But divergent interests also create obstacles for harmonisation initiatives. Regulatory differences between countries may be due to differing risk acceptance levels, pricing models, and circumstances (given the burden of diseases, the vulnerability of populations, the costs of regulation, and so forth) (Zerhouni and Hamburg 2016). Economic and commercial interests in some countries may also underlie blockages in harmonisation processes, for example one country wants to protect its pharmaceutical industry from imports from other countries.

The interests of national policymakers in harmonisation is a critical factor in the operationalisation of the AMA. Those interests also depend on the added value of the AMA – over the benefits due to the intervention of national regulators and RECs. Thus far, the political traction for the operationalisation of the AMA and regulatory cooperation at the continental level is not guaranteed as shown by the hesitation of some major AU MS such as Nigeria and South Africa (which also influence their respective RECs) to sign and ratify the AMA treaty as well as the slow progress in the domestication of the AU Model Law. The domestication of the AU Model Law has not reached the target of at least 25 African countries by 2020 (Ncube et al. 2023). Thus, an important task for this agency will be to determine its priority functions (joint assessments and good manufacturing practice (GMP) inspections, marketing authorisation, pharmacovigilance, safety surveillance, coordination of quality control, or clinical trials oversight), beyond its general coordinating function and in complementarity with the regulatory functions effectively performed by national and sub-regional regulatory agencies.

Policymakers should also be concerned with the financial sustainability of NRAs' funding models, which underpins their efficacy, autonomy and integrity. As the pharmaceutical sector develops and regulatory needs expand, their model should adapt and rely on contributions from the private sector and on charges levied for regulatory services. Furthermore, as the case of Eastern Africa shows (see Box 6), harmonisation could lead to a reduced flow of regulatory activities for individual NRAs and thus lower receipts from the industry and other users. In this case, NRAs may be reluctant to engage in wholesale harmonisation processes. Managing the

tensions between these different objectives is an important task for the regulation agenda of the partnership.

Box 6: Lessons learned from regional regulatory harmonisation processes facilitated by AMRH

The role of the AMA in coordinating and supporting various actors involved in African regulatory harmonisation initiatives could help further the sub-regional regulatory harmonisation processes previously supported by the AMRH and supplement and use resources more efficiently at the levels of countries and regional economic communities (RECs). The AMRH was piloted in the East African Community (EAC), where it contributed to improving capabilities to regulate health products (Ndomondo-Sigonda 2021).[21] In the EAC, NRAs have jointly assessed dossiers through collaborative regulatory procedures (CRPs) (Ndomondo-Sigonda et al. 2017). They have also conducted joint GMP inspections to enable faster product marketing authorisation. CRPs have resulted in a 40–60% reduction in the time from submission to approval for a set of branded medicines. Yet, this pilot project also shows that regional harmonisation processes meet resistance from the part of national actors. The EAC has not been able to establish a licence for the manufacturing and distribution of pharmaceutical products that would be valid for use in all its partner states. The NRAs have retained the sole responsibility of granting marketing authorisations, and some have refused to accept joint decisions. The incentives of NRAs, which obtain a significant portion of their funding from GMP assessments, dossier reviews and other regulatory functions, may have hindered the full implementation of the harmonisation scheme, as the centralisation of registrations would entail a loss in revenue (Dansie et al. 2019). This experience shows that while there is scope for regulatory cooperation, for assessing medicines, inspecting production facilities, quality controls and pharmacovigilance, the incentives as well as interests of national actors may undermine the feasibility of "reliance" (or, mutual recognition of regulatory decisions), whereby one country would rely on the marketing authorisation granted by another country. It also suggests approaches focusing solely on applying good regulatory practices may not produce desired results if they do not take into account the politics of medicines regulation.

Source: From the authors

Although regulatory cooperation for the delivery of health products is a central issue for policymakers, the Africa-EU partnership should also be concerned with other regulatory challenges.

[21] Five of the EAC Partner States have comprehensive medicines laws and autonomous NRAs. All the NRAs have functional registration and GMP inspection systems supported by regional harmonised guidelines, four of them having obtained the ISO 9001:2015 certification.

Box 7: Additional regulatory challenges related to health

Trade regulations can be a critical factor for pharmaceutical production as manufacturers secure supplies of ingredients, other inputs and equipment. High customs duties, lengthy customs procedures and other trade barriers affecting imports of these goods hamper the competitiveness of local producers. The African Continental Free Trade Area (AfCFTA), which aims to facilitate regional trade in medicinal and health products, can play a role in easing the importation of quality inputs and equipment.

The widespread presence of substandard and falsified medicines across Africa, which are largely imported from Asian countries, constitutes a public health threat.

Amongst low- and middle-income countries worldwide, the African region has the highest prevalence of poor-quality medicines with an 18.7% prevalence of substandard and falsified medicines (Ozawa et al. 2018). Porous borders, poor market controls and corruption are then conducive to the trade in substandard and falsified medicines between African countries. As in the case of the West African Health Organisation (WAHO), the objective of reducing illicit and counterfeit medicinal drugs can be adjoined to that of providing quality, safe and affordable drugs.

As vaccine and pharmaceutical production expands and consumption grows in African countries, environmental spillovers can be expected. The contamination of the environment by pharmaceutical effluents also causes the development of resistance to medicines. Putting in place or strengthening existing environmental regulations in African countries is an important area of cooperation between the EMA and the AMA.

Source: From the authors

6. Research and innovation

Key insights

- Strengthening health R&I capacities is a priority for the New Public Health Order, to attain the equitable access and universal health coverage objectives.
- R&I cooperation is also an area where the EU can effectively contribute to the partnership with Africa.
- A key challenge for the partnership is to scale up African public investments in R&I, building on emerging health R&I systems led by African research organisations. Another one is to engage the private sector in strategic partnerships to take advantage of technology transfer opportunities and deliver health innovations that address unmet needs.
- African and European actors need to refine their approaches to building public-private partnerships and mitigating risks for private investors.

6.1. Emerging results

Although scientific production in Africa is growing, the continent produced only 2% of the world's scientific research output in 2015 (UNESCO 2015). African governments provide little funding for science and technology, less than 0.5% of GDP on average in 2019 with large

disparities between countries (South Africa, Egypt and Nigeria account for two-thirds of African domestic spending on R&I). Therefore, strengthening health R&I capacities has become a priority for the AU to strengthen health systems, support infectious disease control, and contribute to the development and production of pharmaceutical products and medical technologies, with a view to addressing locally prevalent diseases.

The European and Developing Countries Clinical Trials Partnership (EDCTP) Joint Undertaking, under the European Union's Framework Programme for Research and Innovation, is the main programme of cooperation with sub-Saharan African countries that focuses on R&I for health. It is a key activity of the AU-EU Innovation Agenda, which, as part of the Global Gateway, supports technological transfer and innovation. The third iteration of the partnership, Global Health EDCTP3, with a budget of EUR 1.6 billion, mainly finances projects conducting clinical trials (in phases II and III) and developing new or improved health technologies and interventions to address the burden of infectious diseases[22] and medical interventions for other diseases.

The successive EDCTP can also be credited for having established regional networks supporting clinical trials and clinical research in sub-Saharan Africa and allowing for the sharing of expertise, clinical research capacities and data. These networks have been formed around the Regional centres of Excellence established with the support of the partnership. In addition, the EDCTP fellowship programme has supported more than 400 postgraduate researchers working on poverty-related infectious diseases in sub-Saharan Africa, thus building clinical research capacity in Africa, which is critical for promoting Africa-led research and development (R&D) agendas at the national and regional levels and African health sovereignty.

6.2. Challenges and opportunities

When it comes to R&I, a number of challenges remain and should be addressed through the EU-Africa Innovation Agenda, which has prioritised public health. One challenge for the Africa-EU health partnership is to encourage African governments to increase public funding of R&D. For instance, EDCTP projects have received limited financial contributions from African governments (Simpkin 2019). While this situation may not affect the effectiveness of clinical trials and research agenda, it may not always encourage ownership by African actors. This situation reflects a broader context where African research organisations continue to rely in large part on international donor agencies for research grants and fellowships (Midega et al.

[22] EDCTP has contributed to the development of a Malaria vaccine. Recently, it developed a simplified treatment for cryptococcal meningitis using a single dose of a liposomal formulation of amphotericin B, which led to an update of WHO guidelines. It also implemented a phase three trial for a new formulation of praziquantel (called arpraziquantel, widely used in mass drug administration programmes for schistosomiasis, a neglected tropical disease, which confirmed its efficacy, safety, and suitability for young children. In December 2023, the EMA adopted a positive scientific opinion for arpraziquantel to treat schistosomiasis in preschool-aged children. Also, it contributed to the development of Fexinidazole Winthrop as the first oral treatment for the East African sleeping sickness, which received a positive opinion of EMA in December 2023 too.

2021). The current period of economic slowdown and high indebtedness in many African countries is also not conducive to the expansion of public investments in R&I.

Another challenge concerns the involvement of the private sector in R&I activities, whether as a provider of financial or technological resources. Globally, the commercial sector is key to health science R&I – pharmaceutical companies are among the top investors in R&I in the health science sector, which is not the case in Africa (Simpkin 2019). Nonetheless, the vaccine manufacturing and technology transfer initiatives launched during the pandemic provide pointers for improving approaches to engaging the private sector. In South Africa, the consortium built around the COVID-19 mRNA vaccine technology transfer hub involved industry and university actors that created a vaccine similar to that of Moderna, which did not require obtaining a TRIPS waiver for a patent or a licence. In Senegal, the MADIBA project to produce a vaccine relied on the R&I capabilities of the Institut Pasteur de Dakar, collaborating with industry actors such as Univercells for development of technologies. According to these experiences, the combination of mature enough local R&I systems, financial incentives and political backing (which can be essential for lifting obstacles to project implementation) is crucial for effectively engaging committed private sector actors and encouraging technological transfer and innovation.

The interlinked issues of pricing of medicines, intellectual property protection, and public support for R&I are crucial for attaining the objective of equitable access. In the pharmaceutical sector, large companies tend to generate high profits from the intellectual protection of their products and technologies, although they have usually received considerable amounts of public support and have benefitted from public infrastructure. Also, some countries in Africa have not fully exploited the Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities for the production and importation of generic health products that are protected by patents. The approach taken by African countries to address this issue is going to be determinant for the effectiveness of their pharmaceutical and health policies.

These experiences suggest that well-targeted and executed public-private partnerships are critical for the development of health innovations, building on long-term public investments in scientific organisations and expertise. The emergence of R&I initiatives in Africa, such as the Regional Centres of Excellence, the Coalition for African R&I and the Alliance for Accelerating Excellence in Science in Africa, provide opportunities to form partnerships and address specific challenges. This partnership approach could also help address the unmet needs of African populations, in particular for NDCs such as cancer and also poverty-related, neglected diseases – in most African countries, prevention and treatment remain severely constrained by the low level of research and awareness about the factors and consequences of these diseases, for hypertension for example (Hédon 2015). The development of R&I networks will also help retain scientists and technologists, including those whose training has been funded under the Africa-EU partnership.

Both African and European actors need to consider the governance of R&I. Many African countries lack up-to-date, unified legislation to regulate the conduct of health research and

policies to direct investments in R&I, while having several institutions in charge of health research and weak coordination mechanisms (Nabyonga-Orem et al. 2021). On the EU side too, close coordination between different programmes will be needed to support a rebalancing of health R&I.

7. Conclusions

7.1. Overall assessment of the partnership in international context

As much as the COVID-19 pandemic was disruptive for AU-EU relations, there has been a silver lining to it. The public health and socio-economic crises that ensued, revealing profound inequalities in access to healthcare services, vaccines and treatments, has compelled African as well as European actors to rapidly make political and financial commitments to remedy the status quo ante. It has also reinvigorated their partnership in the area of health by putting equitable access at its centre while also laying the foundation for better prepared health systems in the face of disease outbreak and environmental risks.

Both African and European strategies elaborated in the wake of the pandemic point towards a closer alignment of their actions, in the framework of a more comprehensive approach to global health – on paper at least. A renewed focus on health system strengthening and UHC is palpable, as illustrated by the 5Cs approach of the Africa CDC, focusing in particular on building resilience of community health systems and health workers to ensure access of health products and services to the last mile. On the European side, the new EU Global Health Strategy integrates the priorities of Africa's New Public Health order, notably the strengthening of public health institutions. These policy developments have also advanced the social dimension of AU-EU cooperation.

At the multilateral level, African and European actors have common interests in the reform of the health security institutions to better manage risks, coordinate responses to future pandemics, and improve access to vaccines and treatments. Their efforts to localise the production of vaccines and establish a new supply system for health products where African would play a more important role – as indicated by the intention of GAVI to contribute to the procurement of vaccines from Africa in the future, is an essential factor of the viability of investment in production systems in Africa. Although they may not have the same view on IPRs and technology transfer, Africa and Europe may also find common industrial, trade and health security interests in the diversification of health product supply chains. And through bilateral cooperation, by strengthening African health institutions, pandemic preparedness, and improving financing, they may contribute to alleviating the contentions in the negotiations of the Pandemic Accord.

Yet, the implementation challenge for this more comprehensive agenda remains. The EC and the Belgian Presidency of the Council of the EU recently launched three additional Team Europe Initiatives for health, one on Health Security following the One Health approach, one on Digital Health, and one on Public Health Institutes, which aims to strengthen the capacities of African

institutions and agencies at the national and regional levels. Also, a new TEI on social protection is intended to improve access to primary and specialised healthcare. Yet, it remains to be seen how these new initiatives will be implemented, work in synergy, and improve health care delivery in a more inclusive way. Another challenge is to maintain the momentum in the bilateral relation and at the multilateral level, as the pandemic spectre fades away. Although new ways of working have been established in the past years (Team Europe), many health initiatives have been launched (on the African side) and Africa-Europe coordination mechanisms have been put in place, the partnership needs to keep different policy areas and actors together towards common strategic objectives. The fact that the Team Europe approach and MAV+ in particular have not always been well understood by African public and private actors suggests that sustained political backing and awareness raising efforts – with policymakers, economic operators and the health science community are both needed.

The response to the pandemic has also accelerated the development of health institutions in Africa in collaboration with European actors, who have played a positive role (for example, support to CDC or AMA). Nevertheless, African countries must take ownership of funding their public health institutions, as an over-reliance on external support, like from the EU, risks financial sustainability of the Africa-led programs. Aside from financing, the approach to PPR has mainly focussed on preparedness and response (e.g through local production of vaccines) than on prevention. Joint efforts between Africa and European actors to address the increases in zoonoses and food-, water- and vector-borne diseases are imperative to prevent future outbreaks, for example through a One health approach.

7.2. Opportunities to make the partnership future-proof

Although it is only part and parcel of the Africa-EU partnership, valuable lessons can be learnt from the operational cooperation focused on access to vaccines, medicines and health technologies during the period of the pandemic. As African and European political leaders were focused on developing vaccine manufacturing capabilities and improving the enabling environment of the pharmaceutical industry, significant progress has been made in this domain in targeted countries, in terms of technological developments, investments in manufacturing facilities and regulatory strengthening. The alignment of African and European policies toward this goal has allowed for complementarities between PAVM and MAV+, with the latter delivering support to countries and regional organisations through different channels (national research organisations, local companies, international companies, WHO hubs, and so forth). The combination of the novel mRNA technology, modular manufacturing facilities that can produce different vaccines in response to various epidemic threats, and digital technologies are enabling more flexible forms of vaccine manufacturing, facilitating the development of productive capabilities in African countries.

Yet, in the case of the COVID-19 vaccine, the amounts of locally-produced doses used for vaccination campaigns in African countries has remained limited, which suggests that a number of hurdles need to be overcome to improve vaccine supply security in African countries. While other vaccines are being produced and deployed in African countries (for example, recently launched Malaria vaccines), reaching the objective set by the PAVM

Framework for Action to manufacture in Africa at least 60% of the region's vaccine needs by 2040 will require sustained efforts.

Policies and investments are needed to support the development of sustainable vaccine and pharmaceutical value chains: there is a whole-of-value chain and diversification agenda to pursue. Developing, producing and distributing vaccines and medicines on a large scale requires securing supplies of pharmaceutical ingredients and having established a cold chain, storage infrastructure, and other logistics capabilities, which are often missing in African countries. Growth in the vaccine industry should also be accompanied by growth in supporting industries to provide raw materials and inputs as well as consumables (vials, sterile bottles, syringes). The pandemic has also been a reminder of the importance of access to diagnostic tests. In recent years, other outbreaks on the African continent (Ebola for instance) have shown the urgency of developing production and distribution capabilities for diagnostic tools.

The analysis of the partnership also shows that in the post-COVID-19 phase, making progress towards the goal of equitable access and supporting the New Public Health Order requires sustained efforts in the areas of medicines regulation as well as R&I. In some African countries at least, significant progress has been in developing regulatory frameworks and moving up the ladder of regulatory maturity, in cooperation with MAV+ and EMA. The fact that some national regulators are ahead of others creates opportunities for cross-country learning and regulatory cooperation to make marketing authorisation processes more efficient and join forces in market surveillance and pharmacovigilance. Sub-regional cooperation for regulatory strengthening and harmonisation has yielded improvements in regulatory performance, for instance in the EAC and West Africa. Yet, as AMA and EMA pursue their collaboration, their support to regulatory agencies and harmonisation schemes should be mindful not only of technical obstacles but also of the underlying financial, economic and commercial interests that stand in the way of harmonisation processes.

In the area of R&I, there are two major challenges: one to boost African government R&I funding for the development of R&I organisations and networks, which not only support equitable access but also public health security; and the other one to engage private sector engagement in concrete, strategic R&I and technology transfer projects with credible market prospects as in the cases of Senegal and South Africa reviewed in this paper. This second challenge requires agile facilitation of partnerships, where European actors can bring in technology, know-how and capital to African countries and public actors can use instruments to lower risks for the private sector.

Stronger public health workforce for Africa is a clear priority in Africa's New Public Order. The EU R&I support has had positive effects on the training of health scientists through the EDCTP and country-level initiatives such as the MADIBA training programme for vaccine scientists in Senegal, in association with a vaccine manufacturing project. Less has been done for the training of health regulatory and intellectual property experts, which remains a gap to address to support the effectiveness of regulatory cooperation given the scarcity of skilled professionals in the regulatory field as well as the pharmaceutical industry. Interventions in the area of human resources for health should ensure that the capacities of district-level health

workers are also strengthened, which play a role in access to quality medicines as well as services.

Digital as a tool offers opportunities to ensure accessible, quality and efficient delivery of health services using technology, towards achieving UHC. Though not a focus of this paper's present analysis, the cooperation on digital health is a growing area of focus for African actors, who seek to leverage the successes with (mobile) technology to reach the last mile. Political ambitions for cooperation on digital and health have been made including in the AU Digital Transformation Strategy for Africa 2020 - 2030, the Africa CDC Digital Transformation Strategy and through EU support in the TEI Digital Health. Past collaborations include the establishment of digital COVID-19 certificates, through the operationalisation of the Trusted Travel Platform (TTP) and the EU Digital COVID-19 certificate (EU DCC). Yet beyond this, it is not yet clear what the priorities and needs from African countries are and whether they can be matched by support from the EU actors. Meanwhile, some countries like Rwanda are charting the course using telemedicine technologies to increase accessibility to health services and advance UHC using cost-effective ways to offer telemedicine to rural communities who would have had to travel to urban health centres.

7.3. How to make the Africa-EU health partnership even more strategic and impactful?

Considerable progress has been achieved in strengthening the Africa-EU dialogue on health. Yet, a frank and open dialogue on health interests and priorities should be strengthened to ensure that interventions respond to African priorities (thus fostering ownership and sustainability) and European interests. This means: i) using whenever possible existing platforms[23] to support informal dialogues - not only for the preparation of formal meetings - where actors can more freely share their interests and constraints. Examples are the high-level dialogue in February 2024 between the AU and EU to strengthen the health partnership, which was followed in March 2024 by the high-level event on the EU-AU partnership in global health for equitable access, organised by the Belgian Presidency of the Council of the EU; ii) for the EU to openly share their interests, including those going beyond development (economic and geostrategic), which would allow identifying common areas of strong political traction. This is even more important given the post-pandemic falling momentum for health; iii) regular review meetings on progress to date and strategic decisions on the Africa-EU partnership should be held to share challenges and lessons learnt. Alternatively, a joint steering committee could be set up to strategically steer and maintain the momentum of the health partnership.

Coordination could also be strengthened at two levels: i) within the Africa-EU partnership, to ensure that Europeans do not come with fully fledged interventions which are then difficult for African actors to steer and influence - this would help avoid Europeans driving the health agenda, and would require African to further coordinate as with Team Europe (which is even more important given the fragmented landscape of health); ii) at the multilateral level by

[23] For example, through thematically focussed ministerials (for example, the Agriculture Ministerial Conferences) or expert dialogues (for example, the AU-EU Human Rights Dialogue and the High-Level Policy Dialogue (HLPD) on Science, Technology and Innovation (STI)) which exist as mechanisms within the AU-EU partnership.

supporting an open dialogue that could translate in common positions in multilateral fora, giving even more weigh for African and European priorities - which could be decisive especially given the uncertainties surrounding the 2024 US elections.

Europeans should keep working with and through African institutions as a means to strengthen their capacities and foster local ownership and sustainability, in line with Africa's New Public Health Order. They should keep providing financial and technical support to inter alia, Africa CDC and AMA, whilst avoiding creating excessive external dependencies and unsustainable models. In this context, Europe should i) support the accreditation of the Africa CDC as an implementing entity of the Pandemic Fund, so as to enhance its resources and autonomy and ii) help AMA secure long-term financing by helping mobilise additional source of funding together with African stakeholders - whether from the AU, the private sector or the Global Medicines Regulatory Harmonization Multi-Donor Trust Fund or other multilateral funding mechanisms.

African and European partners should mobilise and allocate adequate resources based on their respective priorities, responsibilities and capacities, while avoiding creating external dependencies and unsustainable models. This is especially important for R&I activities, where the EU should i) build synergies between its respective R&I programmes (EDCTP, MAV+, other TEIs etc.); ii) leverage development finance wherever this is relevant, i.e. de-risking technology investments, investing in riskier parts of the value chains (see the EIB investment in APIs; Seymour 2020), and riskier segments (health MSMEs); iii) foster a partnership approach between financial institutions for development for risk diversification and co-financing opportunities (see the example of the Medical Credit Fund II) and between these and implementing agencies, and between European and African institutions - which often have a better network and market/risk knowledge. Given the reliance of R&I activities on grants, the Europeans could decide to target this type of efforts to common Europe-Africa illnesses, and/or opt for matching funds to encourage domestic resource mobilisation. Importantly, R&I activities must be geared towards addressing health inequities - hence any financiers should systematically consider health impacts including in terms of service coverage, when looking at investment opportunities.

Beyond financing, the Africa-EU health partnership should sustain their efforts to localise the production of vaccines while promoting the diversification of pharmaceutical and healthcare value chains based on demand and mutual interests. To do so, African and European partners should i) provide in the form of, for example, a study to better understand and assess the market and institutional, current and future demands in Africa for various pharmaceutical products, raw materials, ingredients, consumables and diagnostic tests, which will provide guidance for future public investments. Developing a methodology leveraging existing health database could be en efficient way to collect and update data on a regular basis and push for an harmonisation of indicators and data across African countries). This assessment should lead to i) a better understanding of market opportunities (and gaps) that could be explored (jointly when relevant) by the local and European private sector and which would have a great impact on boosting health service coverage; and ii) prioritisation of disease burdens and major unmet needs for treatments in different regions of Africa to be tackled as part of the Africa-EU partnership. This could also feed into EU–Africa pharmaceutical and healthcare

marketplace and matchmaking events. Beyond the supply side, European partners should i) influence GHIs (GAVI, UNICEF, and others) in a way that translates into the creation of opportunities for African manufacturers to respond and win tenders for vaccine production; and support the implementation of the AU Pooled Procurement Mechanism. This would be key to help consolidate the demand for health products, creating bigger markets and making health products more accessible, affordable and available; and ii) invest in transport and logistics infrastructures - in line with the Global Gateway - to facilitate the distribution of health products even in the remote and rural areas.

From a regulatory perspective, the EMA should support the AMA in honing its regulatory functions at the continent level, while considerations on the varying levels of regulatory maturity across RECs and countries, locally-specific needs, and the expected benefits should also be factored in. Support by European partners should: i) strengthen coordination on regulatory strengthening and harmonisation (including for pharmacovigilance and post-marketing surveillance systems) between the continental agenda and the sub-regional level, to foster equitable access to quality and safe health products; ii) support sub-regional networks of regulatory agencies with anchor regulatory agencies assisting less advanced NRAs; and iii) continue to support the twinning approach for regulatory strengthening, for example, as piloted in Rwanda and Ghana and extend it to other partner countries; and iv) AMA-EMA cooperation programme should also integrate environmental issues in regulatory processes[24] and also the issue of trade in substandard medicines.

Lastly, the partnership should cooperate towards skills development for the health workforce, in particular for the training of biotechnology workforce, health regulatory scientists and practitioners in accordance with African priorities and the EU's GHS ambitions. In support for the AU's theme for 2024 "Educate an African Fit for the 21st Century,"[25] the EU should direct part of the resources of the Global Gateway's investment package for Africa earmarked for education and training to: i) an AMA-led training programme in partnership with the WHO Academy; ii) the harmonisation of the curriculum for national regulatory authorities, the provision of technical training on core regulatory functions, and the strengthening of medicines regulatory expertise in regional networks of regulators so as to facilitate the development of regional markets; and iii) support bottom-up initiatives such as the MADIBA training programme for vaccine scientists in Senegal, with opportunities to scale training to other production hubs.

[24] For example, integration of environmental standards in good manufacturing practices guidelines, making marketing authorisation conditional upon environmental risk assessments, and requiring that pharmaceutical companies report environmental incidents.

[25] Educate an African Fit for the 21st Century: Building Resilient Education Systems for Increased Access to Inclusive, Lifelong, Quality, and Relevant Learning in Africa".

Annex 1: Non-exhaustive list of health-related African strategies

The list below presents some of the main health related strategies developed and implemented by African institutions.

- **Agenda 2063: The Africa We Want.** One of the goals of Agenda 2063 is that citizens are 'healthy, well and nourished and have long life spans.' It plans for an Africa in which all neglected tropical diseases (NTDs) are eliminated and communicable and infectious diseases are brought under control.
- **Africa Health Strategy 2016-2030.** Provides strategic direction on the creation of better performing health sectors, recognises existing continental commitments, and addresses key challenges to reducing Africa's burden of disease.
- **Africa Centres for Disease Control (CDC) Africa CDC Strategic Plan 2023 – 2027**. Provides the key strategic directions of Africa CDC, based on the health agenda for Africa.
- **Africa CDC Digital Transformation Strategy 2023-** Seeks to improve public health outcomes on the African continent through the use of technology.
- **Catalytic Framework to End AIDS, TB and Eliminate Malaria by 2030.** Aims to eliminate AIDS, TB and malaria in Africa by 2030 and sets out to intensify the implementation of the commitments made through the Abuja declaration.
- **Pharmaceutical Manufacturing Plan for Africa.** Catalyses local pharmaceutical production, which, in turn, should contribute to improved public health outcomes through improved access, quality, availability and affordability of vaccines, therapeutics and diagnostics.
- **Partnerships for African Vaccine Manufacturing(PAVM); Framework for Action 2022-** The frameworks lays out a strategy that seeks to scale up the local production of vaccines within the African continent, with the objective of attaining a 60% increase by 2040
- **African Common Position on Antimicrobial Resistance Control.** The AU Heads of State and Government announced a strong political commitment to control antimicrobial resistance (AMR) in Africa through the African Common Position on Antimicrobial Resistance Control and AU Framework for Antimicrobial Resistance Control 2020-2025, officially adopted at the 33rd AU Summit in February 2020.
- **Animal Health Strategy for Africa 2018-2035.** Aims at improving the health and productivity of the animal population to enhance the economic and social welfare of Africans.
- **Health Research and Innovation Strategy for Africa.2018-2030.** Enables Africa to design and lead research and enables active participation of African researchers and innovators in local and international health, health system and medical health technology innovation ecosystems.
- **IHR 2005.** During the 29th Ordinary Session of the Assembly in 2017, the Declaration on Accelerating Implementation of International Health Regulations in Africa was adopted.
- **4D Framework. AU Ministers launched the 4D Partnership Tech Strategy** – which is an agenda to boost synergies and break siloes within the AU community and across the AU, MS, pan-African civil society, private sector and other strategic stakeholders of Agenda

2063. It is a platform for multi-disciplinary, multi-dimensional, multi-departmental and multi-directional collaboration in Africa, powered by artificial intelligence, machine learning, big data and homegrown innovation.

- **Science, Technology, and Innovation Strategy for Africa 2024.** This strategy is the first of the ten-year strategies developed to respond to the demand for science, technology, and innovation to impact across critical sectors such as agriculture, energy, environment, health, infrastructure development, mining, security and water among others.
- **Strategy for Quality Health Infrastructure in Africa - 2022-2030.** African development Bank strategy aiming to support in overcoming gaps in national health infrastructure, which have been exposed by COVID-19 and other health crises.

Annex 2: Priorities of the EU Global Health Strategy

Table 1: Key priorities of the EU Global Health Strategy

Key Priorities	Guiding Principles	Actions
To deliver better health and well-being of people across the life course	1. Prioritise tackling the root causes of ill health, paying particular attention to the rights of women and girls, and to vulnerable populations and disadvantaged groups.	• Prioritise addressing the economic, social and environmental root causes of health and diseases.
	2. Improve equitable access to a full range of essential health services from health promotion to disease prevention and affordable quality treatment, rehabilitation and palliative care to fight communicable and noncommunicable diseases.	• Prioritise addressing the economic, social and environmental root causes of ill-health through a "health in all policies" approach. • Follow a human rights based approach, paying particular attention to the needs and rights of women, children and young people. • Continue to lead the fight against both NCDs and CDs. • Ensure that innovative vaccines, treatments, and diagnostics for new, prevalent or neglected infectious and NCDs are developed and used. • Support the expanded uptake of vaccines against childhood illnesses. • Strengthen support for universal access to SRHR
To strengthen health systems and advance universal health coverage	3. Improve primary health care with built-in surge capacity, and enhance core public health capacities to meet the requirements of the International Health Regulations	• Engage with partner countries to expand access to a basic package of health services covering prevention and care with particular focus on poor and marginalised populations. • Encourage investments in health systems by implementing targeted incentives and increasing accountability. • Foster international standards in pharmaceutical medical devices and technologies.

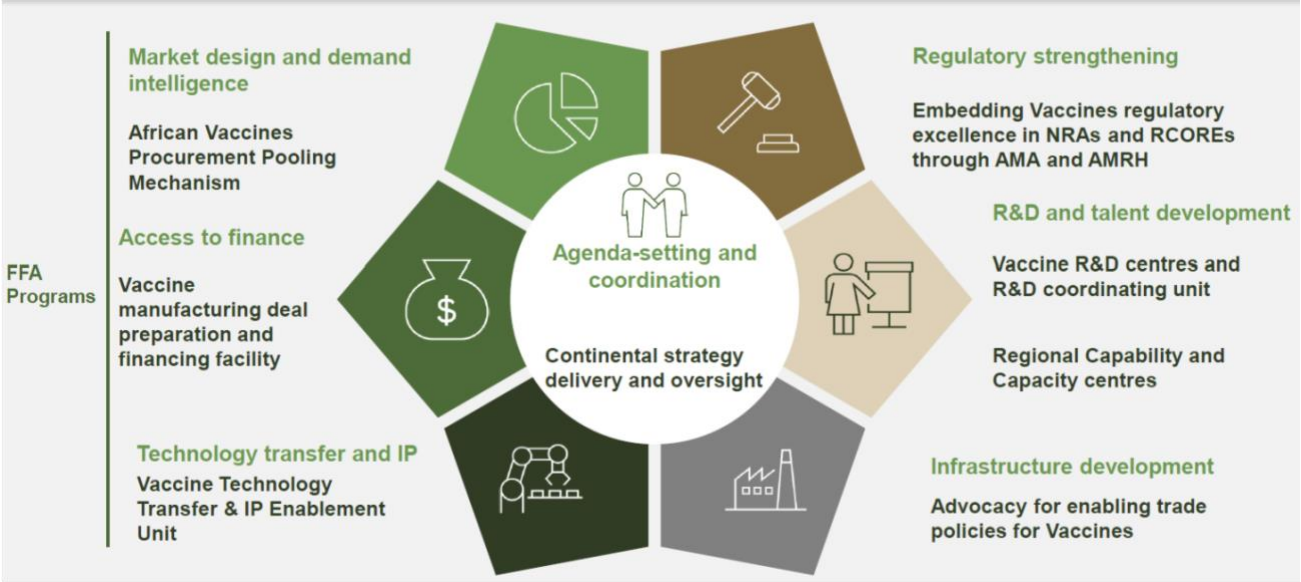
	4. Foster digitalisation as a fundamental enabler.	• Address underinvestment in digital health and care in low and middle income countries. • Build on the EU being pioneers in regulation of health data, digital certificates using the cloud for data sharing, data protection and privacy. • Contribute to shaping the digital health ecosystem globally i.e. rules, norms, standards, interoperability.
	5. Boost global health research to develop the technologies and countermeasures which are necessary to improve health	• Extend international research and innovation cooperation, making research data as open, standardised and interoperable as possible. • Boost support of international processes that strengthen the scientific base for policy action. • Contribute to mutual capacity building through joint undertakings. • Support the design of regulation, production, procurement and delivery to ensure research conducted in low and middle income economies is relevant for local pharmaceutical and health technology production.
	6. Address workforce imbalances and foster skills	• Support partner countries in training, recruiting and putting into action healthcare workers and ensuring their professional development. • Foster mutually beneficial mobility arrangements with partners in a context of health workforce shortages. • Strengthen international cooperation and adherence to international commitments on recruitment, developing reliable monitoring and data collection of workforce and its flows.
To prevent and combat health threats, including pandemics, applying a one health approach	7. Strengthen capacities for prevention, preparedness and response and early detection of health threats globally.	• Prioritise health security on the global health agenda including by designing and implementing the TEI with Africa. • Diversify and build EU capacity of supply chains for critical equipment and

		countermeasures, diagnostics and therapeutics. • Support the development of a comprehensive disease outbreak humanitarian response system. • Expand and strengthen European and global research partnerships
	8. Work towards a permanent global mechanism that fosters the development of and equitable access to vaccines and countermeasures for low- and middle-income countries	• Launch effective surveillance systems that have the capacity to identify pathogens at an early stage and effective research platforms that can readily produce the necessary evidence for quick development and rollout.
	9. Negotiate an effective legally binding pandemic agreement with a One Health approach and strengthened international health regulations.	
	10. Build a robust global collaborative surveillance network to better detect and act on pathogens.	
	11. Apply a comprehensive One Health approach and intensify the fight against antimicrobial resistance	• Intensify work with the quadripartite including WHO, FAO, WOAH and UNEP t6o implement its One Health Joint Plan for Action. • Support the development of and access to innovative medical countermeasures to address AMR, including antimicrobials, vaccines and diagnostics. • Work towards the inclusion of concrete provisions on antimicrobial resistance in the pandemic agreement

Annex 3: Action framework of the PAVM

The Framework for Action of the PAVM is structured along eight programmes, each of which focuses on an enabling factor of production and distribution systems. It provides guidance for pursuing the AUC and the Africa CDC's goal of manufacturing 60 percent of its vaccine needs locally by 2040.

Figure 1: Action framework of the PAVM



Source: AU and Africa CDC 2022

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