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Operationalising pharma manufacturing hubs in Africa: Policy options for the EU

By Karim Karaki and Pamella Eunice Ahairwe

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Health systems in Africa are overdependent on international markets. Africa imports more than 90% of the pharmaceutical products and 99% of the vaccines. While it is costly for individual countries to manufacture pharmaceutical products, adopting a regional approach could help solve this problem. Regional manufacturing hubs can benefit from economies of scale and exploit the potential opportunities that African Continental Free Trade Area and the regional economic communities provide.

Africa aspires to make regional pharma manufacturing a reality. Europe is interested and has already taken steps to support Africa in developing operational regional pharma manufacturing hubs. However, there are several mishaps along the way. This report outlines the main challenges in seven policy areas – coordination, market dynamics, access to technology, trade and regional integration, regulatory framework, skills, knowledge and expertise, and health systems. It explains how these challenges presently undermine the establishment of regional pharma manufacturing hubs.

Addressing the prevailing barriers is a demanding task. It requires all relevant stakeholders in Europe, Africa and beyond to work together in a constructive and complementary way. This report also presents recommendations (as outlined in the executive summary on pages iv, v and vi) for the European policymakers and development partners, including development financial institutions, on how they can support the evolution of sustainable and well-functioning regional pharma centres in Africa.

Table of Contents

List of Boxes

List of Figures

List of Tables

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Acronyms

ACE	Education Center of Excellence
AfCFTA	African Continental Free Trade Area
AfDB	African Development Bank
Africa CDC	Africa Centres for Disease Control and Prevention
AMA	African Medicines Agency
AMSP	Africa Medical Supplies Platform
API	Active pharmaceutical ingredient
ATM	African traditional medicine
AU	African Union
AUC	African Union Commission
AUDA	African Union Development Agency
AVATT	African Vaccine Acquisition Task Team
BII	British International Investment
BMGF	Bill & Melinda Gates Foundation
CGD	Center for Global Development
CSO	Civil society organisation
DFC	Development Finance Corporation
DFI	Development finance institution
EAC	East African Community
EASTECO	East African Science and Technology Commission
ECA	Export Credit Agency
ECDC	European Centre for Disease Prevention and Control
ECDPM	European Centre for Development Policy Management
ECOWAS	Economic Community of West African States
EDCTP	European and Developing Countries Clinical Trials Partnership
EDFI	European Development Finance Institutions
EFSD	European Fund for Sustainable Development
EIB	European Investment Bank
EU	European Union
FDI	Foreign direct investment
FIP	International Pharmaceutical Federation (*Fédération Internationale Pharmaceutique*)
GDP	Gross domestic product
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	Good manufacturing practice

GSSS	Green, social, sustainable and sustainability-linked
IFC	International Finance Corporation
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IPR	Intellectual property right
IUCEA	Inter-University Council for East African
LDC	Least developed country
MDB	Multilateral development bank
ML3	Maturity level 3
MSF	Doctors Without Borders (*Médecins Sans Frontières*)
NEPAD	New Partnership for Africa's Development
NHRS	National health research system
NMRA	National Medicines Regulatory Authority
NRA	National regulatory agency
NTB	Non-tariff barrier
OECD	Organisation for Economic Co-operation and Development
PAVM	Partnerships for African Vaccine Manufacturing
R&D	Research and development
RCORE	Regional Centre of Regulatory Excellence
RDI	Research, development and innovation
REC	Regional economic community
RoO	Rules of origin
RRA	Regional regulatory authority
RVC	Regional value chain
SDG	Sustainable Development Goal
SSA	Sub-Saharan Africa
STEM	Science, technology, engineering and math
UNIDO	United Nations Industrial Development Organization
US	Unites States
WHO	World Health Organization
WTO	World Trade Organization

Executive Summary

Regional integration, industrialisation and trade are seen as building blocks for a competitive pharma manufacturing sector. Pharma production costs associated with manufacturing, materials and machinery, finance and utility services are usually high (UNIDO 2021). African countries that consolidate markets at the regional level create economies of scale, enhance productivity gains, relatively reduce costs and make the possibility of pharma manufacturing a reality. A number of interventions during the European Union (EU) -African Union (AU) Summit echoed this perspective of a regional approach. Particularly, HE. Daniel Ngamije, a health minister in Rwanda, declared that the production of quality health products targets not only the national market but also regions within and outside Africa. In this regard, a notably positive change has happened in the past couple of years with the establishment of the African Continental Free Trade Area (AfCFTA), which connects 1.3 billion people from economies with a combined GDP of over US$3.4 trillion, and aims to liberalise trade between African countries, strengthen productive capacities, and develop infrastructures as well as regulatory frameworks (AUC and OECD 2022).

However, developing effective regional integration with well-developed and functional regional value chains is a complex endeavour (UNIDO 2021). This quest is even more pronounced for the pharma sector which faces several challenges, with some having a more significant impact than others. The success of the regional pharma manufacturing hubs will, therefore, depend on the extent to which the major regional challenges can be addressed to boost the regional industrialisation operations and promote economic diversification, human development and well-being. Addressing the prevailing barriers is a demanding task that requires all relevant stakeholders within Europe, Africa and beyond on the table in a way that is constructive and complementary. **This report contributes to solving this development issue, by providing an understanding of how EU development partners including financial institutions for development can engage at the regional level to support the development of operational regional pharma manufacturing hubs which can benefit African countries.**

Firstly, it looks at key challenges associated with seven major policy areas including; coordination, market dynamics, access to technology, trade and regional integration, regulatory framework, skills, knowledge and expertise, and health systems; and how these continue to hinder the development of regional pharma sector. Secondly, the report provides recommendations for European policy-makers on how they can best support the development of sustainable local productive capacities and more generally the development of the pharma and health sectors in Africa. **The seven policy area challenges and recommendations that EU development partners could implement to foster the development of the regional pharma manufacturing hubs in Africa are highlighted below.**

Challenge 1: Coordination

1.1 EU Member States should engage in (regional) Team Europe Initiatives such as MAV+ to ensure a high degree of coordination between development partners and channelling of resources efficiently.

1.2 African partners, with the support of the European Union (EU), should establish regional platforms to strengthen the cooperation, dialogue and resource mobilisation of African and European actors, and ensure African ownership and leadership.

1.3 To be sustainable, financial support geared towards increasing the supply of vaccines and pharmaceuticals should be coordinated with actions facilitating the consolidation of markets for pharma products and the regulatory framework.

1.4 EU development partners should support the establishment of coordination mechanisms between the regional pharma manufacturing hubs across the different regional economic communities (RECs) to allow for knowledge and experience sharing and foster South-South cooperation.

Challenge 2: Market dynamics

2.1 Donors and financial institutions for development should provide funding for a pooled technical assistance facility focusing on project preparation in the pharma sector.

2.2 Financial institutions for development should mobilise additional private financing through a blended finance approach to support riskier segments of the value chain, such as active pharmaceutical ingredients (APIs) production.

2.3 Financial institutions for development should facilitate/incentivise pharma manufacturers' investments and exports, by developing innovative financial products such as volume guarantees.

2.4 EU development partners should provide support geared towards understanding, assessing and building/consolidating the demand for pharma products to ensure the sustainability of the investments in this sector.

Challenge 3: Access to technology

3.1 Team Europe should provide funding and technical assistance to facilitate technology transfer by providing comprehensive yet integrated support targeting the knowledge ecosystem, upskilling /reskilling, and research, development and innovation (RDI) infrastructures.

3.2 Financial institutions for development such as European Investment Bank (EIB), African Development Bank (AfDB) and European Development Finance Institutions (EDFI) should work collaboratively to provide development finance aiming to de-risk investments associated with technology development.

3.3 Given the lack of traction at the regional level, the EU should provide RDI support at the national level while undertaking political economy analysis in order to shape regional interventions that respond to national interests.

3.4 The EU should support North-South and especially South-South foreign direct investment (FDI) in order to facilitate technology transfer.

Challenge 4: Trade and regional integration

4.1 The EU should support the African Union (AU) in conducting an analysis of the tariffs and non-tariff barriers (NTBs), which may prevent pharma-products trade and the development of cross-border pharma-value chains; and assess the trade and trade facilitation implications of pharma-reg hubs.

4.2 The EU should support the process of harmonisation of standards and their implementation at the regional level.

4.3 EU development partners should finance transport and logistics infrastructures to facilitate the distribution and access to the regional market.

Challenge 5: Regulatory framework

5.1. The EU should help better define the regulatory role of the national regulatory agencies (NRAs), the regional regulatory authorities (RRAs) and the African Medicines Agency (AMA) and in turn the support they require to ensure that they fulfil their regulatory functions in an effective, efficient and timely manner.

5.2 The EU should help regulatory authorities at the national and regional levels build their capacity with a view to ensuring the quality of existing medicine.

5.3 The EU should support the adoption of a coordinated mechanism to facilitate the implementation of the harmonised regulations for improved cross-border pharma industry.

5.4 The EU should support the strengthening of the legal systems to empower them to effectively implement the medical regulations in place at regional and national levels.

Challenge 6: Skills, knowledge and expertise

6.1 The EU should help address the pharma skills and labour shortage, and foster the development of a competent and knowledgeable pharma workforce that is able to respond to African health challenges.

6.2 The EU should support the development of skills observatories at the regional level to track and monitor the pharma skills needed in the regions, in order to identify skills-gaps, and anticipate future needs - especially when linked to digitalisation and development of upskilling/reskilling strategies.

6.3 The EU should support regional health research in the pharma sector, development and building of well-equipped medical laboratories as well as science centres for regulatory authorities and institutions of higher learning

6.4 The EU should support the adoption of favourable labour retention policies within the African continent.

6.5 The EU could support RECs in promoting labour migration policies and mutual recognition of qualifications within their regions, to allow for a more agile and flexible workforce.

6.6 The EU could support the exploitation of traditional medical knowledge and its development to address Africa's health challenges while aligning with international standards.

Challenge 7: Health systems

7.1 The EU could provide technical and financial budget support to increase public spending in the health sector, enabling African countries to effectively equip their health facilities with essential medical equipment, technology and a well-trained workforce.

7.2 The EU should, through its development finance institutions, support the private sector health MSMEs, to enable them to provide affordable health/pharma products and services and close the gaps left by the public sector.

7.3 The EU should support the adoption of universal health insurance to help low-income earners especially women and the vulnerable to access healthcare services.

1. Introduction

The pandemic has exposed vulnerabilities in the African health systems and the risks of overdependence on international markets for pharmaceuticals. Africa imports more than 90% of its pharmaceutical products and about 99% of its vaccines (EC 2021). Such a high dependence on external production for essential products proved to be unreliable during the pandemic when Africa was left with undersupplies of pharma products and more importantly, the much-needed vaccines. The health systems of several African countries also have a common feature of limited resilience. Sub-Saharan African countries on average invest 1.9% of GDP in the health sector, which is less than half of the average investments in East Asia and the Pacific - 4.4% and Latin America and the Caribbean - 4.1% (AfDB 2021). Such a low investment is not sufficient to provide affordable and quality health products and services to all citizens and limits the capacities of African countries in delivering accessible, affordable and quality health products and services.

Building the pharma-manufacturing capacity and strengthening health systems in Africa is a key priority for the African Union (AU) that is widely supported by the European Union (EU) policy-makers.[1] This position is well demonstrated by the recent initiatives announced by the AU and EU, as part of the sixth EU-AU Summit and beyond. The common agenda of the two continents as presented in the EU-AU Joint Vision for 2030 is articulated around two priorities - supporting health systems and vaccine production, and three areas of intervention: investment in production capacities, voluntary technology transfers, and strengthening of the regulatory framework to enable equitable access to vaccines, diagnostics and therapeutics.

Table 1: Indicative overview of some of the key AU and EU initiatives in the pharmaceuticals sector

	Pharma manufacturing	Regulatory framework	Health systems
African priorities and initiatives	• Partnership for African Vaccine Manufacturing and framework for action	• African Medicine Agency implementation	• African Union COVID-19 Response Fund • African Medicines Supply Platform
European support	• Team Europe initiative on manufacturing and access to vaccines, medicines and health technologies in Africa (TEI MAV +)	• Support to African Medicine Agency	• Global Gateway investment in health infrastructure • COVID-19 Vaccines Global Access, COVAX • European Investment Bank support to health systems

Many of the initiatives presented in Table 1 focus on building pharma productive capacities, a key component to ensuring a 'New Public Health Order for Africa' and achieving global public health objectives. Such a plan is not a new ambition for Africa. It has featured on the AU Agenda since the 2000s with the Pharmaceutical Manufacturing Plan for Africa (PMPA) and has now become the prominent focus of the 2021 adopted Partnership for African Vaccine Manufacturing (PAVM). The major objective of PAVM is to scale up local vaccine manufacturing capacities and meet at least 60% of local demand by 2040, especially in regard to: (i) legacy diseases, (ii) expanding diseases, and (iii) outbreak diseases. The Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa (TEI MAV+) aims to support African countries reach this 'bold goal' by contributing to

[1] The health sector is a key priority of the French Presidency to the European Council.

the implementation of the regional pharma manufacturing hubs. In turn, strengthened productive capacities are expected to foster access to affordable and quality pharmaceuticals and increase resilience to future crises and spikes in global demand (UNIDO 2021).

Regional integration, industrialisation and trade are seen as building blocks for a competitive pharma manufacturing sector. Pharma production costs associated with manufacturing, materials and machinery, finance and utility services are usually high (UNIDO 2021). African countries that consolidate markets at the regional level create economies of scale, enhance productivity gains, relatively reduce costs and make the possibility of pharma manufacturing a reality. A number of interventions during the European Union (EU) -African Union (AU) Summit echoed this perspective of a regional approach. Particularly, HE. Daniel Ngamije, a health minister in Rwanda, declared that the production of quality health products targets not only the national market but also regions within and outside Africa. In this regard, a notably positive change has happened in the past couple of years with the establishment of the African Continental Free Trade Area (AfCFTA), which connects 1.3 billion people from economies with a combined GDP of over US$3.4 trillion, and aims to liberalise trade between African countries, strengthen productive capacities, and develop infrastructures as well as regulatory frameworks (AUC and OECD 2022).

However, developing effective regional integration with well-developed and functional regional value chains is a complex endeavour (UNIDO 2021). This quest is even more pronounced for the pharma sector which faces several challenges, with some having a more significant impact than others. The success of the regional pharma manufacturing hubs will, therefore, depend on the extent to which the major regional challenges can be addressed to boost the regional industrialisation operations and promote economic diversification, human development and well-being. Addressing the prevailing barriers is a demanding task that requires all relevant stakeholders within Europe, Africa and beyond on the table in a way that is constructive and complementary.

This report contributes to solving this development issue, by providing an understanding of how EU development partners including financial institutions for development can engage at the regional level to support the development of operational regional pharma manufacturing hubs which can benefit African countries. It analyses some of the inherent challenges that undermine the implementation of a regional approach to pharma manufacturing hubs in Africa and provides recommendations for European policy-makers on how they can best support the development of sustainable local productive capacities and more generally the development of the pharma and health sectors in Africa. The rest of the paper is organised as follows: section 2 provides an overview of the regional manufacturing sector in Africa, and section 3 provides a detailed discussion of challenges being faced and policy options for the EU.

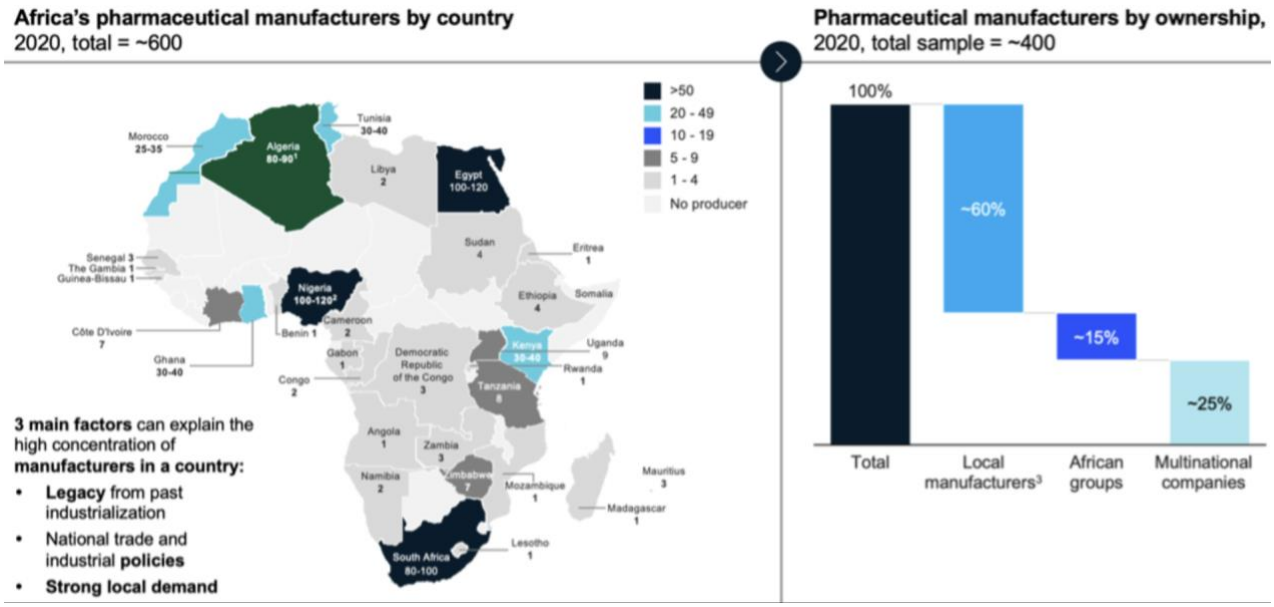
2. Regional pharma manufacturing in Africa

2.1. Overview of pharma manufacturing capacities

Africa is estimated to have 600 manufacturers of essential medicines and 10 producers of vaccines (see Figure 1). 80% of these pharmaceutical manufacturers are concentrated in eight countries: South Africa, Nigeria, Egypt, Morocco, Tunisia, Ghana, Kenya and Algeria. Most of the inputs required for the production of therapeutic medicines are imported and only three of the vaccine manufacturers have drug substance capabilities (UNIDO 2021). The African pharma manufacturing sector is hence characterised by limited capacities that are concentrated in a few countries. These are also not vertically integrated, that is, (i) most companies operate following a fill-and-finish

business model, which limits complementarities, and (ii) the regulatory framework lacks harmonised standards which makes it unconducive for synergies between firms of different countries. The regulatory issue closely relates to the broader issue of fragmented markets that often prevent pharma manufacturers from growing at scale, increasing their competitiveness vis-à-vis international pharma manufacturers, and providing affordable and quality pharmaceuticals to citizens.

Figure 1: Overview of Africa's pharmaceutical manufacturing capacities



Source: CGD 2021

Following the pandemic and the need to upscale pharma capacities in Africa, 15 manufacturing projects have been launched, increasing the existing capacities by threefold (ONE 2022). While these developments are expected to strengthen the resilience and response of African health systems, they should address market needs (both in volume and price) if they are to be financially viable and contribute sustainably to the African industrialisation agenda. This is currently a challenge observed in the case of the pharma manufacturer Aspen in South Africa, which halted production as the demand for COVID-19 vaccines reduced (Barnes and Kuchler 2022). Building pharma manufacturing capacities that are competitive cannot be confined to a narrowly national approach, as all African countries cannot produce vaccines for their own domestic markets. Instead, it should follow a regional approach and ensure that complementarities are established between countries. This might in the long run allow manufacturing plants to be financially viable, sustainable and competitive at the regional level.

2.2. The rationale for a regional approach to pharma manufacturing

A regional approach to pharmaceuticals production would promote access and security of quality medical supplies produced at the regional level including for countries that do not have the capacity to produce these products on their own. Building regional value chains is a key objective of the AU as well as the African Development Bank (as part of the high five areas) and it aims at overcoming the small national market problem prevalent in most African countries. The AU also expects to boost competitiveness and contribute to economic resilience and diversification of the continent, supporting a shift away from raw commodity exports to processing and value-addition activities. In this context, a particular game changer is the AfCFTA, which aims to "promote industrial development through

diversification and regional value chain development" including in the pharma sector. This objective materialised with the recent establishment of the pharmaceutical initiative pilot project led by UNECA, and implemented in ten countries. In line with the AfCFTA, this pilot project aims to increase efficiency gains by 5% to 15% and local production by 10% and "*to develop the capacity of African countries to ease the burden on their health systems through three pillars; facilitation and advocacy of local production, continental pooled procurement and harmonized regulatory, quality, and standards of medicines and related medical products*" (UNECA 2022a).

This study deep dives into the regional dimension of pharma manufacturing, reflecting the nature of the recently established regional pharma manufacturing hubs. Regional manufacturing hubs have been established in several African countries including Egypt, Ghana, Morocco, Rwanda, Senegal and South Africa.[2] These are intended to work as a hub and spoke model. The hubs are projected to have greater technical capabilities/maturity, while the spokes are still at a more initial stage and will contribute with specific inputs along the value chain. This would enable the hub and spoke model to lower the cost of self-contained pharmaceutical facilities, enhancing the financial sustainability of regional manufacturing hubs (CGD 2021). However, when put in practice, the concept of regional pharma manufacturing hubs is confronted with a number of challenges. This study deep dives into seven of them (see Figure 2 below), illustrating for each the nature of the challenge, and potential recommendations that could be implemented in order to tackle them.

Figure 2: Policy areas included in the scope of the report

Source: *Authors*

[2] Nigeria also aims to become a regional pharma manufacturing hub, while other countries such as Kenya are being considered. For more information see: Onyedika-Ugoeze (2022) and Bilal et al. (2022).

3. Challenges and policy options for the EU

3.1. Coordination

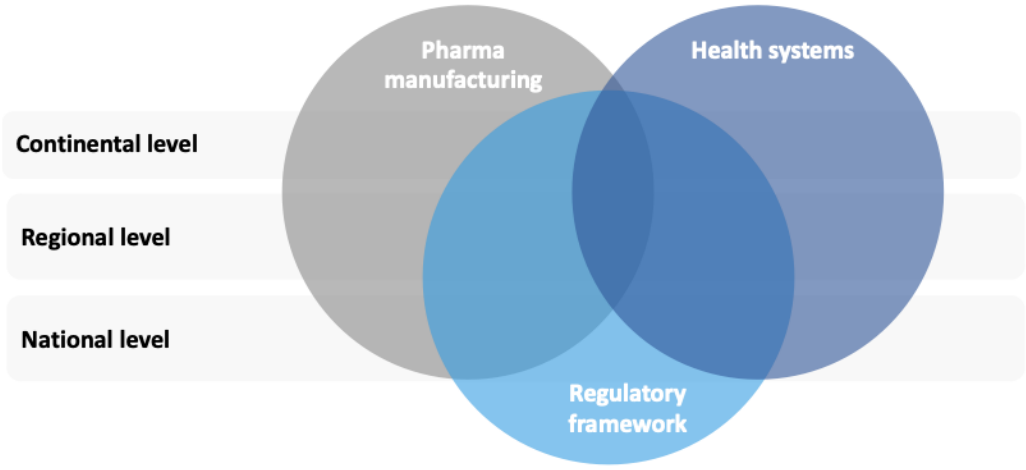
A. Challenges

Lack of effective Africa - EU coordination - including in the health sector - might impede the relevance of EU interventions and their impact on the ground, limiting the space for African ownership. The Team Europe approach allows Europeans to speak with one voice, optimising the use of resources and avoiding the often-observed fragmentation of interventions/priorities when they are developed individually by member states. This can help facilitate dialogue with AU member states and a better understanding and overview of EU interventions. However, coordination at the EU level takes time: very often, EU member states have to first agree internally (between e.g. the Ministry of Foreign Affairs, their development agencies, development finance institutions (DFIs) etc.) on the specific support to be provided. Once this is done, a proposal is put at the EU level to get approval and attract the EU and other EU member states and refined following the feedback received. Only at that moment are African actors involved. This leaves limited time/margin of manoeuvre for the AU and its member states to react. This was one of the issues observed during the preparation of the EU-AU Summit.

Besides, the AU does not necessarily have the same type of coordination mechanism and processes as its EU partners. Coordination between Team Europe and Africa is hence a challenge, which needs to be addressed to ensure ownership and leadership by AU member states in the implementation of interventions targeting the pharma sector. Importantly, the EU and its member states should support but not be the driving force of such processes. In addition, better coordination would allow exploring and leveraging of local knowledge and solutions (indigenous knowledge in medicine, local community workers etc.), which are often overlooked.

Coordination between different interventions also remains a challenge yet this is a crucial factor in determining the impact and sustainability of support interventions. Coordinating interventions is also a matter of prime importance. As argued by recent studies, manufacturing health products is "*a perfect example of the need to adopt an integrated approach and coherence among many policy areas when addressing productive capacity and health sector issues*" (Bilal et al. 2022). Regional pharma manufacturing hubs inherently touch upon industrialisation, technology transfer, trade, regional integration, logistics, health systems, et cetera. Reaching a transformative impact in the pharma sector necessitates that these policy areas be dealt with in a coordinated manner. Moreover, interventions between the continental, regional and national levels should be reinforcing each other as presented in Figure 3. They should also adequately consider national political priorities, notably industrialisation ambitions, and should ideally align with industrial policy objectives (Karkare et al. 2022).

Figure 3: Coordinating interventions to foster synergies and coherence



Source: *Authors*

Coordination between regional pharma manufacturing hubs is also important to make sure that they contribute to the objectives of the Partnerships for African Vaccine Manufacturing (PAVM). For instance, in West Africa, the EU provides support to regional pharma manufacturing hubs in Senegal and Ghana, while Nigeria recently announced its intention to become a regional hub. There are hence three regional hubs for one region - raising questions about (i) their level of complementarity and coordination; (ii) the sustainability of the pharma manufacturing capacities in place in each of these countries.

B. Recommendations

1.1 EU member states should engage in (regional) Team Europe Initiatives such as MAV+ to ensure a high degree of coordination between development partners, and to channel resources efficiently.

The Team Europe approach allows channelling financial support in a coordinated and efficient manner to support regional pharma manufacturing hubs in Africa through the EUR 1 billion MAV+ initiative. In this context, EU member states (including through their development agency, DFI, or Export Credit Agency - ECA) can provide additional support to the TEI MAV+, based on their expertise and interest - including skill acquisition and research, development and innovation where relevant. By working through a TEI approach, EU actors will be able to optimise the efficiency of resources used, while being able to deploy them in strategic areas of interest in coordination with other donors.

1.2 African partners, with the support of the EU, should establish regional platforms to strengthen the cooperation, dialogue and resource mobilisation of African and European actors, and ensure Africa's ownership and leadership.

A lesson from the EU-AU Summit was that the AU and its member states should be involved early on when decisions/interventions are being developed so as to ensure a certain degree of alignment between the latter and their priorities and needs. While Team Europe is already involved in the continental PAVM, which provides space for

dialogue through its various working groups, it could be valuable to have such dialogue at the regional economic community (REC) level. The dialogue could be hosted by the RECs themselves or the regional capability and capacity centres or regional centres of regulatory excellence as foreseen as part of the PAVM or alternative platforms. The choice of the host should be strategic: it should: (i) respond to the ambitions and objectives of Africa and EU partners; (ii) leverage regional champions with expertise but also a strong desire to move forward the pharma and health agenda; and (iii) generate traction among regional member states, i.e. should incentivise countries to engage at the regional level on some key issues.

This dialogue would allow the EU and African partners who are involved on the ground to align interests and concretely discuss their analysis of local needs and priorities, experience and lessons learnt. This will guide the EU in addressing challenges that are a top priority for Africa and forge ways to foster cooperation and resource mobilisation, in line with AU development ambitions, e.g. the Africa Agenda 2063. More specifically, regional platforms could be used to raise awareness about African and European national and regional initiatives, share mapping and planned interventions (for example regarding markets) to ensure a coherent, coordinated and integrated approach, and support an open dialogue among the African countries and donors. This would in turn strengthen coordination, build trust and help align interests in building resilient and sustainable health systems. In order to have space for frank and constructive discussions, the room should be made for informal dialogues. These informal dialogues could be effective ways to involve African partners in the early stage of thinking of developing interventions supporting the pharma and health sector, in a way that supports their ownership and leadership.

1.3 To be sustainable, financial support geared towards increasing the supply of vaccines and pharmaceuticals should be coordinated with actions facilitating the consolidation of markets for pharma products and the regulatory framework.

Investing in the capacities can only be sustainable if well-coordinated with actions that can enable consolidation of markets, e.g. the harmonisation of standards at the regional level. Without such coordination, pharma manufacturers will not be able to achieve the necessary economies of scale to become price competitive vis-a-vis international pharma companies, and additional investments in productive capacities might also fail in the mid to long term. Financial institutions for development, EU development partners and African partners should act in a coherent manner, by coordinating investments and regulatory framework support to ensure that an increased supply meets (regional) market needs. Beyond the issue of the regional harmonisation of standards, support for the regulatory framework and capacities of national and regional regulatory authorities should consider how to further improve the business environment and attract private investments in the sector. An example of such coordination between investments and initiatives targeting the regulatory framework and institutional capacities is taking place in Senegal where the EIB financial support to the *Institut Pasteur de Dakar* is complemented by the AFD investments in strengthening the regulatory framework.

1.4 EU development partners should support the establishment of coordination mechanisms between the regional pharma manufacturing hubs across the different RECs to allow for knowledge and experience sharing and foster South-South cooperation.

To strengthen the dialogue between European and African actors, a continental platform that could be set up as part of the PAVM, should be established to foster synergies (as illustrated in Box 1), knowledge and experience sharing between different regional pharma manufacturing hubs (in Senegal, South Africa, Rwanda and Ghana). This would support the uptake of efficient production innovations, and more generally share good practices and lessons

learnt. To do so in a meaningful way requires investing resources in a proper monitoring and evaluation framework at the regional pharma manufacturing hub level. The latter would track the progress of the regional hubs, analyse bottlenecks and draw lessons learnt, which could be used for other hubs and/or interventions in the pharma and health sector.

Box 1: Germany support to APIs production in Rwanda

The German pharma company BioNTech is expected to supply Rwanda, Senegal and potentially South Africa with modular plants allowing these countries to produce mRNA vaccines. Importantly, the modular plants focus on the production of the mRNA vaccine drug substance - an essential input for vaccine production. Based on this knowledge and experience, it is also expected that the modular plants will be used to produce other vaccines than BioNTech's COVID-19 vaccine - and notably its investigational malaria and tuberculosis vaccines.

The last step of the production process, fill-and-finish, can be carried out within the country but also in other partner countries in Africa. For instance, it is expected that part of the drug substances produced in Rwanda will serve a fill-and-finish plant in Ghana. This shows that synergies can be built between African countries when it comes to the production of pharmaceuticals. GIZ, present in both Rwanda and Ghana through the Team Europe Initiatives, likely played a role in making the link between BioNTech and those two regional manufacturing hubs.

Source: Based on BioNTech 2022, Politico 2022

African partners, together with the support of Team Europe, could support e.g. the establishment of a knowledge and evaluation component in the form of an observatory as part of the regional pharma manufacturing hubs initiatives. This would help build knowledge, which could then be fit into future development initiatives. This would also facilitate South-South collaboration and learning. Several AU institutions such as Africa CDC and EU member states (Belgium, France and Germany) are involved in two or more regional pharma manufacturing hubs, and could hence play a stronger role in supporting the coordination between regional hubs.

3.2. Market dynamics

A. Challenges

A first challenge relating to regional pharma manufacturing hubs and market dynamics is the choice of the locations for the hubs. Many policy analysts have argued that the location decisions were barely based on market rationale. It would be ideal to have a regional manufacturing hub in countries with existing or advanced pharma manufacturing capacities, albeit, this was not the case for some of the selected production centres. While South Africa and Senegal already had some pharma manufacturing capacities, Rwanda would be starting from scratch. As a matter of fact, for the East African region, policy makers and researchers have suggested that Tanzania and Kenya appear to have been stronger candidates for hosting the pharma manufacturing regional hub. This shows that the choice of where to put a regional hub might have been based more on the political than the economic rationale. Although both economic and political arguments are important, relegating the market behind the political dynamics may challenge the implementation of regional pharma manufacturing hubs, which follow a regional industrialisation (and a hub and spoke) type of approach to reach public health objectives.

Moving from macro to micro-level concerns, pharma manufacturers need capital to conduct the research and development (R&D) activities, establish the manufacturing plant according to the World Health Organization (WHO) good manufacturing practices (GMP), run activities and expand their business at the national and regional level. Access to affordable finance is hence crucial for pharma companies at each stage of the value chains. **At the same time, the pharmaceutical sector is perceived as a risky sector to invest in** for the following reasons:

1) it is characterised by a low level of maturity in most African countries;
2) there is a high level of international competition;
3) economies of scale and hence competitiveness is limited by the lack of harmonisation of standards within RECs;
4) SMEs often have limited collaterals, credit history or solid business plans to support their investments (see Box 2); and
5) there is a lack of market intelligence (e.g. market data and forecasts on both the supply and demand side), making business cases hard to build (more information below).

Commercial banks hence offer the pharma companies limited or expensive financial products (e.g. in terms of interest rates - 15% to 25% or the collateral required). The uncertainty of their long-term business model also makes financial institutions to offer them finance for a short maturity period, which is often inadequate. For financial institutions for development, this means that they cannot invest without the support of the grants from the willing donors either in the form of investment grants or technical assistance.[3] The level of these risks, however, is not uniformly spread throughout the pharma value chain. Pharma manufacturers producing APIs may face more difficulties in accessing financing than those engaged on the fill and finish processes. This is often due to the innovative and at times the complex nature of their operations which makes them fall into the relatively riskier category. All these issues, in turn, affect the development of a strong pipeline of bankable projects in the pharma sector.

Box 2: The investment business case of the pharma sector in Africa

Following the COVID pandemic, several African countries increased investments in their vaccine manufacturing capacities to respond to the health crisis by meeting the urgent and prime need for vaccines as the continent's demand far outstripped the supply. However, exceptions exist. In South Africa, e.g. this perspective radically changed in 2022 when the production of vaccines was registered to be higher than the actual demand (Adepoju 2022). These hindrances raise questions on the viability and sustainability of investments in selected regional hubs.

To be financially sustainable, investments in the pharma sector regional hubs must have a solid business case. Vaccines or other pharma products that are manufactured must meet the demand needs of the market. Their prices should be competitive vis-a-vis international pharma manufacturers. African pharma manufacturers also need to widen their market share by leveraging national and regional markets to gain economies of scale. However, trading beyond the borders requires harmonised standards, a condition that is yet to be met for the notion and ambition of regional pharma hubs to successfully take place.

It is clear, with the experience of Aspen, that understanding and assessing the demand for pharma products is one of the key challenges for pharma manufacturers and investors. During the COVID pandemic, the initiatives to support the African pharma sector were fast tracked to respond to the urgency of the crisis but the focus has now shifted towards developing solutions that are financially viable and competitive. A thorough understanding of the demand for pharma and vaccines products is therefore required. However, this is encountered with a problem of the largely missing data. Beyond assessing the demand, understanding some of its drivers and constraints is equally

[3] In fact, to be effective such support should account for 20% to 50% of the overall investment, when it is about the construction of a manufacturing plant.

important. Misinformation and limited awareness about the purpose and benefits of vaccines continue to affect the intake for COVID-19 vaccines in Africa (Kaledzi 2021; Cotterill 2022). Investors and donors who have considered these barriers are trying to enlarge the scope of their interventions beyond COVID-19 vaccines to address other important needs that disrupt the market. Beyond this, a needs assessment is necessary to better understand how African pharma manufacturers can strategically contribute to public health objectives, while remaining competitive in market terms.

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. Initiatives like GAVI, Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), the Africa Medical Supplies Platform (AMSP) or the African Vaccine Acquisition Task Team (AVATT) shape the pharma market by launching call for tenders to source important amounts of pharma products to support eligible developing countries health systems. As such, these would source such products from the African producers as long as they meet their price specifications. Some donors are already aware of this and are, e.g. through GAVI, trying to put in place a premium they are willing to pay to support newcomers such as African manufacturers, allowing them to compete with other international actors. However, it remains to be seen: (i) where newcomers could carve out a niche that could help them to become price competitive in the longer term; and (ii) whether such initiative can be expanded beyond GAVI.

While investing in the pharma sector may be risky, it is important to highlight that international financial institutions may also have their own biases towards African actors, similar to the "perception premium" (Fofack 2021). Additional due diligence requirements, checks and requests for information are usually part of financing Africa and this may be the same challenge with investing in African pharma manufacturers, making the process resource consuming and delaying the overall investment processes. If such a proposal for financing was coming from a European or US player, there would be more trust and this would easily translate into more streamlined processes and requirements. This could be understood under a perception that international financial institutions may have a limited experience and network within partner African countries and their pharma sector. However, at the same time, this perception premium could prevent African pharma manufacturers from accessing finance, leading to a missed opportunity for investment in what would be profitable projects with a potential to contribute to the public good.

Pharma manufacturers are also one of the key targets of the AfreximBank and are currently exporting their products. However, increasing their production requires sufficient capital to finance their growth and expansion stages. This would also help them seek to access new regional market opportunities. The internationalisation of pharma manufacturers can lead to competitiveness and efficiency gains, generate more employment opportunities, reduce poverty, and increase foreign exchange earnings (Appiah et al. 2019). Trade finance plays a key role in financing trade flows between countries by mitigating risks involved in a trade transaction (AfDB 2020; GTR 2022). It helps businesses manage the risk of not receiving payment for exports and provides guarantees to partners, assuring them that they will get money for imports (EIB 2018). While most African banks have trade finance related products, the supply is far from addressing the demand given the estimated gap of more than US$100 billion in 2020 (AfDB 2020). Unmet demand is slightly higher for fragile and low-income countries relative to middle-income countries. With the pandemic and the depreciation of African currencies, commercial banks adopted a more risk averse behaviour, reducing their lending (GTR 2020). In fact, this gap increased with the effect of the pandemic - US$5 billion, and is expected to undermine businesses expansion and growth. Governments, including their export credit agencies also play a role in facilitating international business expansion. This is particularly relevant in case of market failures where risks and costs can be too high. According to TXF Data, Africa accounted for US$35.5 billion worth of ECA-supported debt, making the region the second-most active globally in 2020 for ECA-supported financing.

B. Recommendations

2.1 Donors and financial institutions for development should provide funding for a pooled technical assistance facility focusing on project preparation in the pharma sector.

Technical assistance in the form of advisory services, capacity building programmes and technology transfer complements traditional financial instruments in enhancing the impact of external assistance. It would help strengthen the abilities of the financial intermediaries, allowing them to better mitigate lending risks. It might also help final beneficiaries by supporting them in the development of viable business models and by upgrading their capacity to manage investment projects. This is particularly relevant when investing in least developed countries (LDCs), innovative projects with a strong potential for sustainable development impacts, and expansion and internationalisation of businesses (AfDB 2022).

A technical assistance facility can be established and funded by donor agencies and financial institutions for development with the aim of operating at the continental or regional level and could be employed to provide funding for feasibility studies, technical, legal and economic studies, project preparation and development -including, among others. Such support would support the development of a pipeline of bankable projects to achieve the PAVM objectives and strengthen links between regional hubs. As a continental or regional facility, it would also support the cooperation between financial institutions for development and donors at the upstream level, i.e. before investments are made. This would in turn ensure a strong policy steering and attract more donor investments with the financial institutions for development.

Box 3: Examples of partnerships between financial institutions for development

As part of its Partnership for Global Infrastructure and Investment, the US International Development Finance Corporation (DFC) provided a grant of US$ 3.3 million for technical assistance to *Institut Pasteur de Dakar* for "*early-stage project development for an industrial-scale flexible multi-vaccine manufacturing facility in Senegal with potential annual capacity of millions of doses of COVID-19 and other vaccines, potentially using both viral vector and mRNA technologies*" (USA 2022). Other financial institutions for development joined this effort, namely the IFC, AFD and EIB. In parallel to this operation, the EIB provided €75 million in a sovereign loan financing package, which might be complemented by additional resources from other institutions. This shows that the support provided and partnership between financial institutions for development cover both sovereign and private sector operations.

Importantly, the portfolio of projects covered by the facility should not be restricted to large projects only (e.g. €100 million and above). It should take into account smaller-scale projects - micro-, small and medium-sized enterprises (MSMEs) based on their degree of innovation and environmental and social impacts. Financial institutions for development usually underinvest in MSMEs because of their higher level of risks and transaction costs. Equally important, the facility should favour projects with different scopes in terms of pharma products and inputs (e.g. pharmaceutical flask), based on solid business cases, e.g. consider market needs, gaps, price and volume.

2.2 Financial institutions for development should mobilise additional private financing through a blended finance approach to support riskier segments of the value chain, such as APIs production.

The EU can mobilise additional finance from financial institutions for development (including multilateral development banks, development finance institutions, public development banks and also the private sector) through blended finance to support the different stages of the pharma value chains. This approach is particularly

useful in (i) supporting riskier segments in the value chains; (ii) attracting private sector investments; and (iii) positioning the added-value of the EU in the context of regional pharma manufacturing in Africa. For example, addressing the supply of active pharmaceutical ingredients (APIs) in Africa remains a key challenge that limits the extent to which the pharma value chain in Africa can be made self-reliant. The EU and its member states, can utilise their financial institutions for development and the interested private sector players to boost the existing efforts that are aimed at mobilising additional finance to support the pharma sector in Africa. This will go a long way to closing the continent's demand and supply gaps in the production of APIs, and facilitate the vertical integration of the pharma sector. Guarantees such as those provided under the EFSD+ would be relevant in mitigating the high risks for investors. They are also one of the most efficient instruments to attract private investments.

2.3 Financial institutions for development should facilitate/incentivise pharma manufacturers investments and exports by developing innovative financial products such as volume guarantees.

A few financial institutions for development are exploring the potential to develop innovative financial instruments and trade finance related products such as volume guarantees (see Box 4), pre-shipment finance programmes for distributors, as well as transaction guarantees - specifically those targeted at MSMEs (Sommer 2021). Such innovative financial instruments could subsidise pharma manufacturers, helping them to meet the high operational costs, increasing their productivity both locally and for exporting within and outside the continent.

Box 4: Use of innovative financial instruments by financial institutions

British International Investment (BII) for instance has provided a volume guarantee to reduce the commercial risk and ensure that manufacturers sell a given number of pharma products. This allows them to sell additional supplies into new markets at affordable and sustainable prices (Attridge and Gouett 2020). BII has also through *MedAccess*, "*partnered with the Clinton Health Access Initiative and Hologic, a global diagnostic supplier, on a volume guarantee agreement to reduce the price of viral load testing and extend the scope of testing to include HIV, Hepatitis B, Hepatitis C and Human Papilloma Virus*" (ibid). However, the use of volume guarantee should be complemented by reforms targeting the harmonisation of standards. This will ensure that the manufacturers can exploit further business opportunities in the region and build on their capacities upon the receipt of volume.

Besides developing innovative financial instruments, financial institutions for development should work together with ECAs and trade finance institutions, notably the AfreximBank (see Box 5) to provide pharma companies with adequate and affordable (trade) financing. This is already the case of some financial institutions for development such as the AfDB, AFD, IFU and KfW. The latter for instance provided a US$250 million loan to Afrexim to support the development of the productive capacities of the pharma sector across Africa and foster Africa's industrialisation objectives and preparedness against future pandemics and other health issues (Afrexim 2022). More synergies can be created between financial institutions for development and ECAs without interfering with their respective development and commercial mandates.

Box 5: The role of AfreximBank in supporting the development of the African pharma sector

The AfreximBank, a pan-African multilateral trade finance institution, is involved in several different ways in supporting the development of the African pharma sector. First, it provides trade finance products to the companies in the pharma manufacturing sector, a key target area of its industrialisation and export development pillar under its fifth strategic plan (2017-2021). Second, it also facilitates discussions around the harmonisation of pharmaceutical products and medical devices in Africa, an important element that influences the consolidation of markets and internationalisation opportunities of pharma companies. Third, it signed cooperation agreements with international institutions such as the EIB or KfW, some of which focus specifically on supporting pharma manufacturing.

2.4 EU development partners should provide support geared towards understanding, assessing and building/consolidating the demand for pharma products to ensure the sustainability of the investments in this sector.

There are several complementary ways in which the EU development partners could support African partners in addressing and/or overcoming the lack of market data, a problem that continues to affect private sector investments. First, EU partners should:

1. Support African health systems to digitalise and improve the collection of health data. This can help private sector actors understand the scale of pharma needs. In addition, the EU could also leverage data and information from civil society organisations (CSOs) who are already active in the sector. All in all, this would help get a better understanding and assessment of the market needs, thus lowering perception risks.
2. Support the demand for locally produced COVID-19 vaccines through utilising existing collaborations with global organisations such as GAVI - which benefit from significant EU funding, GFATM, AMSP and AVATT. This can be achieved through providing additional funds and incentivising these organisations to pay a premium for locally produced vaccines and pharma products. Technical assistance could also be used to help the EU and EU funded global organisations to develop a strategy towards sourcing pharma products from newcomers, helping strengthen the latter's public procurement processes. Last, following GAVI's example with their product menu for vaccines supplied by UNICEF for GAVI, the EU development partners should encourage the procurement agencies they support to provide indicative commitments of vaccines and other pharma products 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.
3. Help African countries tackle the issues of misinformation and foster awareness around the benefits of vaccines, which affects their demand. 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 should be essential here in fighting social media misinformation in both public and private platforms.
4. Look beyond COVID-19 and focus on building long-term capacities that are geared towards developing vaccines for other and rampant health challenges such as polio or measles. Efforts should also be made to support the development of new vaccines to fight old diseases such as malaria (Kuchler 2021). Throughout these operations, the EU should support African manufacturers as they identify niche markets, where they could have a competitive advantage vis a vis the Global North international enterprises.

3.3. Transfer of technology

A. Challenges

The vaccine industry depends heavily on the development of capacity for biomedical research and development. In this context, access to and transfer of technologies plays a key role in the local manufacturing of health products. New approaches and technologies can enable Africa to leapfrog innovations, as shown in the case of e.g. telemedicine, drones, big data analytics, mRNA (Ogweno 2022). In the pharma sector, an array of different technologies can be leveraged to open up new opportunities for pharma and health industry development.

At the same time, transfer of technologies is affected by the legalese of intellectual property rights (IPRs), an issue that is currently being highly debated. At the World Trade Organisation (WTO) level, discussions are ongoing for a TRIPS waiver, which would allow third countries to produce the vaccines but also therapeutics and diagnostics. Recently, the Quad's – South Africa, India, the EU and the USA – "draft ministerial decision on the TRIPS agreement" showed that this ambition does not leave up to the original TRIPS waiver proposal put forth by South Africa and India, and supported by over 100 countries (WTO 2022). In particular, the scope of the current draft focuses on the vaccine related patent without including therapeutics and diagnostics. However, the proposal mentions the possibility to enlarge the scope following the six first months of implementation. Second, eligible countries are those which exported less than 10% of the world's vaccines in 2021, which excludes only China, the US, and the EU (MSF 2022). Third, the agreement is meant to cover predominantly domestic needs, though it opens the doors for exports directly or indirectly to eligible countries. Based on the above, individual markets in African countries appear to not offer sufficient scale to manufacture COVID vaccines competitively.

Beyond the IPRs issue, manufacturers need to have the necessary capacities (knowledge, skills and expertise) and resources to successfully manage the technology transfer as well as technology development (Berger et al. 2010). However, this is not a given as government support in the field of research, development and innovation is limited. In fact, most AU member states lack the financial and technical capacities to support skills development, science, research ecosystem, and scale up health innovations and technologies uptake (WHO 2020a). Investment in research and development as a share of GDP stood at 0.51% in 2018, a 0.02 percentage point increase from 2014. This is well below the 2.13% in East and South-East Asia. Within the AU, there are also great regional disparities. In 2016, almost two-thirds of African domestic spending on R&D came from three states: South Africa, Egypt and Nigeria (Simpkin et al. 2019). While public financing is essential, the private sector can also play a key role in funding research, development and innovation activities. Pharmaceutical companies are among the top investors in R&D in the health science sector but this is barely the case in Africa, which has a few businesses with a dedicated R&D department to oversee product development and technology transfer (Simpkin et al. 2019).

The regional economic communities (RECs) have initiated efforts to better coordinate and support the acquisition of technologies including through R&D activities by fostering collaborations between countries and institutions (Yongabo and Göransson 2020). An example of such an endeavour is the establishment of the East African Science and Technology Commission (EASTECO) and the Inter-University Council for East African (IUCEA) in East Africa, that facilitate research, development and innovation activities. **Despite these regional initiatives, most of the efforts geared towards accessing and transferring technologies seem to happen at the national level.** Indeed, the inter-regional collaboration in Africa comprises 2% of all East African research, 0.9% of West and Central Africa, and 2.9% of Southern Africa (Simpkin 2019). This observation is also echoed by the findings of the African Science, Technology and Innovation Forum, which noticed limited progress regarding the collaboration between RECs and member States

to "*develop action plans, mobilize adequate resources for implementation, and also for monitoring and evaluation of the recommendations of science, technology and innovation forums during the intersessional period*" (UNECA 2022b). Despite commitments, national interests continue to dictate the involvement of member states in a regional approach to access to and transfer of technologies and the lack of traction for a regional approach often reflects competing interests among countries that undermine regional objectives (Byiers et al. 2021).

B. Recommendations

3.1 Team Europe should provide funding and technical assistance to facilitate technology transfer, by providing a comprehensive yet integrated support targeting the knowledge ecosystem, upskilling/reskilling, and Research, Development and Innovation (RDI) infrastructures.

TRIPS negotiations have led to little progress thus far. As the position of the quads is not likely to evolve in the coming months, focus should be put on accompanying measures that will need to be put in place to facilitate countries and the access to technology by their private sector. Following the 2022 EU-AU summit, the EU supported the WHO selected six African countries (Egypt, Kenya, Nigeria, Senegal, South Africa and Tunisia) to receive the technology needed for the production of mRNA vaccines. For South Africa, this will be transferred through Afrigen and is intended to empower the country to produce vaccines, medicines and diagnostics locally. The proposed technology hubs could broadly focus on technologies beyond vaccine production to include therapeutics and diagnostics, thus addressing in the short-term one of the gaps observed in the TRIPs waiver.

Additionally, support that is directed towards promoting access to and transfer of technology should go beyond the COVID-19 vaccine to ensure that the African pharma sector can respond to other market needs, e.g. neglected-tropical diseases (NTDs), which affects 47 African countries and 400 million people (WHO 2022). This support would accelerate the development of relevant vaccines and medicines and help the AU in dealing with diseases that continue to affect the continent. Such a development is paramount for, for instance, the malaria vaccine, which has taken about 35 years to be developed (ONE 2022). The EU could also support African countries in the implementation of the Global Health EDCTP3 JU initiative, which is the largest R&D partnership in the history of Africa-Europe cooperation, amounting so far to €1.6 billion (DSW 2022). The scope of the Global Health EDCTP3 JU initiative covers diseases such as HIV & AIDS, tuberculosis, malaria and NTDs, and it includes the preparedness to avert future epidemics of these diseases. Assistance should also be geared towards facilitating access and transfer of technologies that can be repurposed to respond to market changes as evidenced in the case of modular processes and facilities, which allow repurpose of vaccine manufacturing capacities of viral vectors for the advanced therapy medicinal products sector to combat neglected communicable diseases (Markarian 2020).

Additional financial support is also needed to facilitate capacity building programmes to enable technology transfer. This is vital in situations where the pharma manufacturers may lack the necessary technology, human capacity, or R&D and innovation infrastructures. The EU can provide funding and share expertise geared towards skills development programmes, education and training institutes. This would go a long way in strengthening the general knowledge ecosystem and would be an enabler for private sector-led technology development (UNCTAD 2014). Such assistance is also essential in lowering the costs of recruitment by the pharma manufacturers. However, these interventions will need to be coordinated within the EU, through the Team Europe approach, and Africa to avoid possible fragmentation and incoherence.

3.2 Financial institutions for development such as European Investment Bank (EIB), African Development Bank (AfDB) and European Development Finance Institutions (EDFI) should work collaboratively to provide development finance aiming to de-risk investments associated with technology development.

The EU can leverage partnerships with financial institutions for development and donors. European DFIs (particularly the BII, FMO and Swedfund) currently work together as part of the Medical Credit Fund II, which supports innovations that can strengthen medical product value chains. This programme targets mostly start-ups, which are often perceived as one of the riskiest segments. Assessing the progress of these institutions could provide useful lessons learnt for the implementation of the EU Investing in "young Africa initiative." This collaboration between DFIs is even more important for technology development in high-risk investment environments as it allows sharing risks and leveraging additional private capital via blended finance programmes (e.g., as currently being implemented by Alecta and Sida) to support the pharmaceutical manufacturing regional hubs. Additional financial institutions for development should come together around pooled mechanisms to set up, say investment or guarantee funds, that could help spread the risks between different actors, and mobilise more private investment.

3.3 Given the lack of traction at regional level, the EU should provide Research, Development and Innovation (RDI) support at the national level while undertaking political economy analysis in order to contribute to the shaping of regional interventions that respond to national interests.

While there may be a rationale for the EU to support RDI activities at the regional level through the RECs to optimise resources and support regional integration, the situation on ground shows that RDIs activities at the regional level have limited traction. This does not mean that supporting RECs in RDI activities is irrelevant but it could mean that the vital role of RECs is undermarketed. The Economic Community of West African States (ECOWAS), through its Research and Innovation Support Programme, provides competitive annual grants to research teams from the subregion with a focus on problem-solving research. Partly as a result of these efforts, Ghana became a key collaborator for Burkina Faso, Liberia and Sierra Leone in 2017–2019 (UNESCO 2021a). However, regional support should respond to the needs and interests of member states in order to be effective. Building complementary interventions between the national and regional levels requires having a thorough understanding of the interests and constraints of public and private sectors in different countries. This ultimately drives and shapes the extent to which interventions and policies will be implemented. Conducting political economy analysis could help explore the interaction of a range of actors and factors that shape domestic politics, and how they interact with regional, continental, and international relations (Byiers et al. 2022). This would in turn inform the EU and its member states on how they could best engage at the regional level, in coordination with their programmes and interventions at the national level.

3.4 The EU should support North-South and especially South-South foreign direct investment (FDI) in order to facilitate technology transfer.

South-South FDI is more conducive to technology transfer than North-South FDI (Gorg et al. 2017). This may be explained by the fact that the technology gap between firms is less important, and the market conditions for the diffusion of technology (such as skilled labour, appropriate firms' incentives, technology maturity) are also closer. African institutions and development partners should exploit this opportunity and explore ways in which they can support South-South FDI as a means to acquire the much-needed technologies. Such South-South FDI flow could be cross-regional within Africa, or international with e.g. India or China.

The EU and its member states through their involvement in the regional manufacturing hubs should provide funding for the support of B2B matchmaking platforms targeting pharmaceutical and health actors, allowing firms to engage more easily and with limited transaction costs. The platform African Business Coalition for Health, which aims to support the health and wellbeing of the African population and "*expand access to higher-quality health services by leveraging capital, managerial capacity, and know-how from the private sector*" could be leveraged in this context (UNECA 2021a; Jere 2019). The EU has also been active in promoting North-South collaboration through the EU–Africa pharma and healthcare marketplace and matchmaking events. These partnerships have proved to be crucial during the pandemic - with firms like BioNTech partnering with *Institut Pasteur de Dakar* in Senegal for the delivery of start to finish factories (Petesch 2021).

Besides, non-compliance with GMP was found to be one of the major factors preventing FDI in the pharma manufacturing sector as this inherently limits the market for exports. Therefore, in addition to the support for a pharma matchmaking platform, the EU should also collaborate with its African counterparts to set up a technical assistance facility to help African pharma manufacturers build their capacities in compliance with the GMP. This would make Africa pharma businesses more attractive as investment destinations.

3.4. Trade and regional integration

A. Challenges

Trade agreements, and in particular the African Continental Free Trade Area (AfCFTA) can help facilitate the free circulation of pharmaceuticals. By connecting markets across 55 countries, the AfCFTA offers access to a continental market composed of 1.3 billion people, and with a combined GDP of US$3.4 trillion (World Bank 2020a). This could have an impact on pharmaceuticals trade, where 10% of African pharma exports are intraregional - often serving the Eastern and Southern Africa markets (Holtz 2021; IMF 2021). To realise such a potential, the AfCFTA will need to address several challenges pertaining to trade and trade facilitation policy areas, as described in the Table 2.

Table 2: The AfCFTA and the pharma sector

AfCFTA focus	Main concerns and challenges for the pharma sector
Tariffs	Developing countries temporarily suspended tariffs to attract importation of essential medical products during the pandemic (Tondel and Ahairwe 2020). However, sub-Saharan Africa often applies an average of 10% tariff rates on medical products compared to the 2.9% in developed countries (ITC 2020). These tariffs also vary depending on the complexity of the medical product: the more complex it is, and the lower the tariff rates are and vice versa (IMF 2021). While over 70% of Sub-Saharan African countries offer preferential tariff rates to other sub-Saharan African countries on some medical products, the differences in tariff rates between African and non-African suppliers of medical products are often small (ITC 2020). In addition, current negotiation on Rules of Origins (RoO) may negatively affect the liberalisation of vaccines and pharma products especially those under the fill and finish category. Products produced partly or fully locally are exempt from tariffs when exported. Most of the vaccines and to a lesser extent pharma products operating according to a fill-and-finish business model would more likely be subject to tariffs, which might make them relatively expensive for the African market.

Non-tariffs barriers	Compared to the EU average of about 10%, over 50% of African businesses find it difficult to import medical products due to non-tariff barriers (ITC 2020). These include inter alia conformity assessment, rules of origins, charges and taxes, pre-shipment inspection and other formalities etc. (ITC 2022). The issue of harmonisation of standards also plays a crucial role in the trade of medical products (Bilal et al. 2022).
Trade facilitation	The pandemic showed that logistics - including transportation, cold chain, and service delivery - can greatly undermine the deployment of vaccines. Africa scores poorly in this area, trailing behind all major regions in the six categories of the World Bank Logistics Performance Index Database (World Bank 2018). As a result, "*delays at customs are estimated to add 10 percent to the cost of imported goods, which is higher than the average impact of tariffs in some cases*" and vaccination rates are lower than in countries with better logistics performance (IMF 2021).
Lack of harmonised standards	An additional challenge that will need to be addressed in order to consolidate markets, relates to the harmonisation of standards at the regional and through the forthcoming African Medicine Agency (AMA) at the continental level. This would allow expanding access to quality, safe, and effective pharmaceuticals in Africa. Currently, most countries have their own standards, which increases complexity and opportunities to use standards as a non-tariff barrier (Mwangi 2016). Recently, a Ghanaian pharma manufacturer was sharing his difficulties in exporting pharmaceuticals to neighbouring French-speaking countries, while it was easier to do so with Nigeria - which tends to close its own market to foreign firms (Karkare et al. 2022). More efforts are hence required to tackle this issue. Besides, standards should also be applied to indigenous medicines, for which the WTO has issued guidelines (WHO 2007).
Intellectual property (IP)	The IP regime in Africa varies strongly across countries and it is mostly characterised by limited capacities and infrastructures, save for a few countries such as South Africa. Consequently, patents are granted after a long timeframe (Wolters Kluwer 2019). Additionally, Africa is currently faced with the limited use of Trade Related Aspects of Intellectual Property Rights (TRIPS) public health flexibilities (Vawda 2021). It also has a low number of patents that are mostly concentrated in a few countries such as South Africa and Cameroon (Motari 2021).

These challenges can be addressed at the national, regional and continental levels, often in complementary manner. In this regard, the RECs can play a key role in facilitating trade, building institutional capacities and harmonising regulatory standards. It is up to member states to put the regional policies into practice, however, for these policies to be successful, they should respond to the needs of the member states.

B. Recommendations

4.1 The EU should support the AU in conducting an analysis of the tariffs and non-tariff barriers (NTBs), which may prevent pharma-products trade and the development of cross-border pharma-value chains; and assess the trade and trade facilitation implications of pharma-reg hubs.

Multilateral and bilateral donors can support the development of the pharmaceutical regional value chains by supporting the identification of tariffs and NTBs barriers within the AU that may prevent pharma-products trade and the development of cross-border pharma-value chains. With the pharmaceutical industry, it is often difficult to distinguish between non-tariff measures with a protectionist purpose and those relating to simple health regulations, e.g. requirements for registration to ensure safety and efficacy (UNECA 2021b). Donors could facilitate efforts that are intended to assess the implications of this on the AfCFTA design and implementation. They should

also support the assessment of the implications of trade by the pharma regional hubs and the related trade facilitation.

Beyond tariffs and non-tariff barriers, donors could also support the implementation of the AfCFTA phase 2 which will focus on competition policy, investment protection and intellectual property rights. Facilitation of AfCTA phase 2 would have a major impact on the capacity of countries and encourage them to be more innovative while creating avenues for them to access the necessary technologies.

The EU and its member states can also provide technical assistance by funding studies and analysis through the TEI - "Support to the African Continental Free Trade Area" on the AfCFTA implementation. This exercise could be conducted by African Think Tanks such as Kenya Institute of Policy Research and Analysis or the International Trade Centre that may collaborate with EU based Think Tanks to share knowledge and experiences. Such an initiative should also include considerations for EU private companies to participate in the value chain and potentially address the trade-related bottlenecks. Additional studies could shift the focus from the technical aspects related to the AfCFTA to its implementation by analysing the political economy dynamics that will shape and influence the extent to which this continental agreement will be implemented successfully.

4.2 The EU should support the process of the harmonisation of standards and their implementation at the regional level.

At the policy level, the EU and its member states could further support the harmonisation of standards to ensure that quality health products can circulate in given regions based on agreed and internationally recognised quality standards and processes. This in turn will help consolidate markets and strengthen the trust in regionally produced pharmaceuticals.

Through using the existing networks and creating new ones, the EU can share knowledge and expertise on standardisation of medical regulatory frameworks to help Africa harmonise its regulatory systems in line with international standards. This is partly being done, e.g. EMA in collaboration with European Commission, EU member states (e.g. Belgium, France and Germany) and the Bill & Melinda Gates Foundation (BMGF) have pledged to support AMA with more than €100 million for a period of five years. This will come to support the first stages of AMA such as strengthening regulatory capacity, promoting collaboration, and sharing of technical expertise including with Regional and National Regulatory Authorities behind (European Commission 2022). The EU support will mostly be focused on countries that have been selected to host the regional manufacturing hubs, i.e. Rwanda, South Africa, Ghana and Senegal. It will aim at helping them meet the WHO minimum standards on effective regulatory oversight for quality local vaccine production (European Commission 2022). However, this assistance can also be extended to other countries that demonstrated a potential for manufacturing vaccines, pharma and other medical products.

The EU and its member states should also provide technical assistance to regional organisations in charge of the design and implementation of such standards (e.g. the West Africa Quality Programme in West Africa). Additionally, they should engage the private sector to raise awareness on quality standards while tailoring the role of the national and regional organisation to national needs and interests. The EU and its member states should also support the development analysis that looks at the interests, incentives and constraints at the national level and how these shape and influence the implementation (or lack of) of regional standards. For instance, national regulatory agencies (NRAs) income relies on revenue from dossier approval and expedited waivers requested by purchasers, creating financial disincentives for harmonised product registration process (Kaufman et al. 2021). In turn, this analysis should inform its interventions (and those of other donors) to mitigate challenges / blockages and exploit opportunities

that can promote harmonisation of standards. This is important, as regional hubs promote intraregional trade but also raise the question of the added value of different AU member states in the pharmaceutical value chains.

4.3 EU development partners should finance transport and logistics infrastructures to facilitate the distribution and access to the regional market.

Pharmaceutical value chains require specialised structures and processes involving the establishment of well-coordinated regional value chains (RVCs), cold chain, and sustainable transport infrastructure. The EU and its member states could leverage their existing support to trade corridors such as Trade Mark East Africa, or its equivalent in West Africa, to integrate additional measures (e.g. development of cold chains and laboratory) targeting specifically the pharma value chains.

Multilateral development banks (MDBs) could also play a role in financing the development of sustainable transport infrastructures by providing financial instruments such as guarantees or subordinated loans to attract local and international private investments. African governments could also explore the potential to use green, social, sustainable and sustainability-linked (GSSS) bonds to access cheaper finance through the capital market. MDBs could leverage EU instruments to this effect, and notably the EFSD+ and its windows on connectivity (sustainable transport and energy), human development and sustainable finance.

3.5. Strengthening the regulatory framework

A. Challenges

Harmonisation of standards across countries and regions is an essential component of consolidated markets. However, to land well in practice, harmonised regulatory frameworks need to be accompanied by strong institutions at national and regional level, with regulatory agencies that are able to support and enforce these standards. These can also essentially tackle the issue of e.g. falsified pharmaceuticals while ensuring that African citizens can access affordable and quality health products.

Although Africa has achieved progress in its regulatory systems overtime, building the capacities of the regulatory agencies remains a key challenge and priority that needs to be addressed at the national and regional levels. At the national level, several countries have expressed their intentions to reach higher WHO maturity levels. This endeavour can be supported and coordinated at the regional level to ensure a common approach and processes that could help build trust and credibility. However, meeting such objectives requires several challenges presented in Table 3 to be addressed.

Table 3: Concerns of the medical regulatory systems in Africa

Regulatory systems focus	Main concerns and challenges for the pharma sector
Regulatory capacity	Regulatory authorities at continental, regional and national levels have limited capacity to perform core regulatory functions. At the global level, only 26% of National Medicines Regulatory Authorities (NMRAs) have the capacity to carry out core regulatory functions (Dube-Mwedzi et al. 2020). Previous findings also showed that 7% of the NMRAs in sub-Saharan Africa (SSA) had moderately developed medical regulatory capacity (Ndomondo-Sigonda et al. 2021). The lack of the well-trained and experienced regulatory professionals and shortages in institutional capacities bar NMRAs in African countries from adopting and promoting good medical practices. This continues to lead to poor evaluation of medical products and at times inefficient market surveillance.
Weak regulatory systems	With the exception of Western Sahara, all African countries have either authorities, agencies, bodies or administrative units that perform medical regulatory functions (Ncube, Dube and Ward 2021). However, a few of these are robust and mature. In 2018, Tanzania was assessed as the only African country with a stable, well-functioning and integrated regulatory system of maturity level 3 (ML3) (Khadem Broojerdi et al. 2020). Since then, other countries such as Ghana - 2020 and Nigeria and Egypt - 2022 have achieved ML3 (WHO 2022). Although 40 of 46 African countries have medical legislation, about 15% of NMRAs are legally mandated to perform all the critical regulatory functions of marketing authorisation, pharmacovigilance, post-market surveillance, quality control, and clinical trials oversight (Ncube, Dube and Ward 2021). Weak, inconsistent and underperforming regulatory systems are caused by a number of factors, including poor processes and management structures, missing and yet necessary medical policies, especially for medical devices, diagnostics, vaccines; and limited funding to build the necessary infrastructure (Ncube, Dube and Ward 2021; WHO 2019a; WHO 2017a; PATH 2016).
Fragmented medical regulations	Roles and responsibilities between the continental, regional and national level regulatory bodies, authorities and agencies are not always well defined or coordinated. Before the AMA, the African Medicines Regulatory Harmonisation (AMRH) initiative had been adopted at continental level to promote harmonisation of regulatory frameworks, albeit, there is still a long way to go to achieve the set harmonisation objectives. Fragmented medical regulations are costly to enforce across regions and within countries. The absence of a clear, effective, properly functioning and coordinated regional bodies that can provide harmonised regulatory services across borders also leaves medical product manufacturers and distributors faced with longer approval delays (4-7 years for drugs to be used in SSA), heighten supply chain costs and discourage medical manufacturers from entering the African markets (Barton et. al. 2019).
Incoherent legal frameworks	Africa still lacks legal frameworks at the regional levels to enforce the implementation of regional harmonised regulatory standards. Although RECS (e.g EAC through the EAC Medicines Regulatory Harmonization) have tried to harmonise their regulatory frameworks, there is no clear strategy on how the national legislations of different countries are supposed to change to implement these changes (PATH 2016). The problem of dysfunctionality of laws at regional level has its basis on ineffectiveness and non-compliance with the medical regulations that exist at national levels due to corruption and elite capture of the legal systems. This challenge

was loud during the COVID-19 pandemic, when countries allowed the use of herbal drugs to treat COVID-19 without the appropriate legal systems to foresee their registration and clinical trials. Generally, national and regional incoherent and inefficient legal frameworks allow substandard and falsified medical products to circulate freely on the market through the cross-border trade, threatening lives and creating mistrust in medical products, e.g. one every ten medical products on market in developing countries is either substandard or falsified (WHO 2018). WHO after surveying 40 countries (16 from African) also shows that 70% of these lack legal provisions to permit fast-track clinical trial authorizations and 50% lack those to permit emergency-prone product registration procedures (WHO 2019).

B. Recommendations

5.1. The EU should help better define the regulatory role of national regulatory authorities (NRAs), regional regulatory authorities (RRAs) and AMA and support their capacities to ensure that they can perform regulatory functions in an effective, efficient and timely manner.

Regulatory authorities in Africa operate under complex legal frameworks, ambiguous definitions, responsibilities and mandates marked by regulatory gaps and overlaps (AU 2012). Indeed, not all national regulatory authorities perform the regulatory functions. Although 40 of 46 African countries have medical legislation, about 15% of NMRAs are legally mandated to perform all the critical regulatory functions of marketing authorisation, pharmacovigilance, post-market surveillance, quality control, and clinical trials oversight (Ncube, Dube and Ward 2021). When medical regulatory authorities that perform regulatory and non-regulatory functions are faced with resource and human capacity constraints, they often try to prioritise one over the other. To avoid such inefficient tradeoffs, there is a need to explicitly define what should be expected of regulatory authorities at national, regional and continental level.

With the forthcoming implementation of the AMA, the functions and operationalisation of the national and regional regulatory authorities, and how they fit within the wider AMA framework should be stated with clarity. Functions of regional authorities at all levels should endeavour to complement and build on one another, rather than overlap, to make them efficient and effective and improve their relevance in view of their respective target, objectives and the sought-after impact. AMA is intended to support NMRAs through minimising administrative bureaucracies, increasing harmonisation of regulatory requirements and providing technical backup (IFPMA 2021). The EU should provide support to facilitate the NMRAs, in cooperation with AMA, and ensure that these agencies execute all the essential regulatory and non-regulatory functions.

The EU and its member states can provide technical assistance to support regulatory authorities develop clearly defined responsibilities and functions. In this process, the EU should support the inclusion of the private sector in these discussions as it is the ultimate user of the services of regulatory authorities. Inclusion of the private sector will help link regulatory authorities with the trade discussions, enabling NMAs and AMAs to take on practical solutions that ensure policy coherence. For instance, in Ghana, the Food and Drug Authority (equivalent of the NRA) ensures the compliance of standards by pharma manufacturers, but also provides advice and support to private sector actors on how they could address the witnessed gaps. However, monitoring the activities of the private sector requires fast tracking technology that some NMRAs may lack. The EU donors can also provide targeted financial and logistical support, supporting them to ascertain the essential instruments that can be used to facilitate the overseeing of implementation of essential regulatory functions including registration, licencing, inspection and quality requirements at national, regional and continental level and across all the value chain stages (production, transportation, marketing and consumption, manufacturers, distributors).

5.2 The EU should help regulatory authorities at the national and regional level build their capacity with the right specialised scientific knowledge that can develop the necessary regulatory frameworks for the old and new, complex and urgently needed pharmaceutical products.

Attaining mature regulatory systems requires Africa to have a dynamic and high-quality human and institutional capacity that is well equipped to regulate old medical products while also continuously updating regulations to meet the new scientific developments based on current innovations and technology. Africa needs to build the capacity with the right science knowledge to regulate local pharma production at national, regional and continental levels. While the establishment of AMA will benefit national and REC regulatory agencies with technical guidance and build capacity through collaboration and education, the EU can also provide complementary support, particularly technical assistance. The EU can, for instance, support the Africa Higher Education Centres of Excellence (ACE) which have already supported more than 14000 postgraduates in science fields including agriculture and health, paying particular attention to those wanting to specialise in medical products regulation and taking into account regional and national disparities (World Bank 2020).

The EU can also provide collaborative support to the eleven Regional Centres of Regulatory Excellence (RCOREs) established by the New Partnership for Africa's Development (NEPAD) under the AMRH programme to help perform various regulatory functions including pharmacovigilance, quality assurance and quality control, registration and evaluation, clinical trials oversight, licencing, inspection and surveillance of manufacturers, importers, exporters, distributors and dispensers of medicine. Supporting these centres to build a knowledgeable, well-trained and qualified regulatory personnel can promote the regulatory quality of pharmaceutical industries and ensure that products on the continent are abiding by the WHO standards. To achieve this, the EU can leverage existing partnerships within Europe and Africa, e.g. European and Developing Countries Clinical Trials Partnership (EDCTP), Partnerships for African Vaccine Manufacturing, NRAs, AMAs, among others which already bring European and African partners together in this essential aspect. Capacity building activities should also include regulations around local herbal medicines, in line with internationally recognised pharmaceutical practices. Such new capacity building programmes should also ensure clear information flow from regulatory institutions to the industrial sector (Ndomondo-Sigonda 2021).

5.3 The EU should support the adoption of a coordinated mechanism to facilitate the implementation of the harmonised regulations for improved cross-border pharma industry.

At the regional level and with the foundational framework provided under the African Medicines Regulatory Harmonisation (AMRH) initiative which is part of the Pharmaceutical Manufacturing Plan for Africa (PMPA), Africa is now establishing the African Medicines Agency (AMA). AMA is expected to be essential in facilitating the adoption and harmonisation of regulatory policies and standards for medical products at the national, regional and continental level (AU 2022; IFPMA 2021). AMA will support National Medicines Regulatory Authorities (NMRAs), Regional Economic Communities (RECs) and Regional Health Organisations (RHOs) in revamping Africa's access to safe, quality and efficacious medical products. Yet at the moment, it still needs to attract the political will of all African countries. As on 13 May 2022, only 19 out of the 55 African Union states had ratified and deposited the AMA treaty. Achieving harmonised and effective regulatory structures requires strong international cooperation at continental and regional levels which is coupled with great political will and leadership from different heads of states to ensure that all the essential legalities are met for the proper implementation of the regional regulatory harmonisation agenda in a coordinated and coherent way.

As more and more countries ratify and deposit the AMA, the EU - via the European Medical Agency (EMA) is already being very resourceful to the African Union at an early stage, supporting AMA and NRAs adopt science-based harmonised standards that are internationally recognised as discussed in 4.2. The EU can further build on its current investments (e.g. the 2019 funding for Ethics and regulatory capacities) to provide tailored financial support that is aimed at building strong networks and promoting policy dialogues among, e.g the WHO, AMA, AMRH, AMRH, NRMAs, AVAREF, CDC, and ICDRAs, with the end goal of strengthening the harmonisation of medical regulations at the centralised (African or regional level) and decentralised (national) levels. The EU can also provide additional funding to, especially LDCs, to support the harmonisation efforts and close the gaps left by national governments. Under the EAC MRH for instance, countries like Uganda have failed to make their funding contribution and EAC MRH partly relies on external donors (e. World Bank, EU, BMGF) to close the funding gap left by national governments (PATH 2016). Harmonised regulatory standards will solve the fragmentation issue and ease cross-border trade in medical products within the AfCTA as manufacturers and distributors deal with few centralised systems regarding the marketing authorization of their medical products.

5.4 The EU should support the strengthening of the legal systems to empower them to effectively implement the medical regulations in place at regional and national levels.

Legal structures determine the degree of functionality of the medical regulatory systems. Sufficient and strong legal frameworks which are well implemented promote good regulatory practices and ensure that regulatory and ethical policies in place are abided by throughout all the medical product value chains. At the regional level, a suitable legal framework is required to ensure that pharmaceutical/vaccine manufacturers operate based on medical regulatory standards set by vaccine regulatory authorities including NMRA, REC regulatory agencies and AMA (PAVM 2022). Highly skilled capacity is necessary to ensure that the right law provisions are passed, however, it is not the sufficient condition for securing that they are complied with, e.g. through inspecting, controlling and monitoring of the medical value chains. Within EAC, several countries have enacted laws that mandate their regulatory authorities or agencies to regulate pharmaceutical products and medical devices but the extent to which this is done in practice remains debatable (PATH 2016).

Legal systems also necessitate transparent legal institutions that are not vulnerable to corrupt officials and which put public health needs above firm profits or any form of individual or institutional bribery. These legal systems should be developed at all national and regional levels to ensure that firms that engage in illegal practices do not take advantage of weak legal frameworks and institutions in some countries to have their way in producing and distributing substandard or falsified medical products. At the continental level, the Africa Union (AU) has established the AU Model Law on medical products regulation that is supposed to ensure that the right medical products are developed, tested and scaled up for a greater health impact under the provisions of the regional harmonised regulatory systems (Ncube, Dube and Ward 2021). The AU Model Law needs to be implemented at the REC level and subsequently at the national level, however, this needs extensive technical and financial support.

The EU and its member states can support the strengthening of the legal systems in many ways. First, it can support NRAs and RRAs build the right legal capacity that can develop the necessary legal frameworks and provide the enforcement labour force to ensure transparency and accountability. Secondly, it can provide technical capacity, through financing acquisition of the necessary technology and tools which can help countries and regions to monitor how medical market players abide by the standards and regulations in place. Thirdly, the EU can also engage in policy dialogue and play an advocacy role in influencing African countries to develop the political will and leadership to enforce the existing regulatory systems at national level and international level.

3.6. Skills, knowledge and expertise

A. Challenges

Finding skilled workers is no easy task, as there is currently a shortage of skilled workers in the health sector, including in the fields of pharmacology, biology and chemistry (ITC 2022). While Africa's higher education system is evolving, less than 12 universities provide vaccinology courses or engage in vaccine-related pre-clinical studies (IFPMA 2021b). In addition, the education systems of some countries have been assessed to be more theory based and less practical to train scientists that can innovate and invent new scientific solutions. The lack of essential infrastructure (e.g. equipment, well-equipped laboratories and research centres), institutional capacity, and the right education structures, prevents some African countries from building a strong academic base, which can attract more young people into the medical and health science research fields. Those who are currently enrolled are also missing the opportunity of being trained in the latest advanced health science developments. Such barriers continue to affect sub-Saharan Africa, e.g., the region currently has the least number of researchers (FTE) per million inhabitants of this 124, in comparison to 1476 for East and Southeast Asia as of 2018.

African countries do not invest enough in research and development. At national level, countries invest limitedly in their national health research systems (NHRS), with public investments in health science research standing below 2% of the national health expenditure target (Wenhan et al. 2021). In SSA, less than 50% of the countries have budget lines for health research, a national health research policy, health strategic plan, legislation governing research, hospitals with ethical review committees to review clinical research proposals, and about 33% have a knowledge translation platform (Kirigia et al. 2015). Poor investments in research and development prevent the development of the necessary capacity that is knowledgeable and skilled in pharmaceuticals, including products and technology. Limited investments in the pharma industry also discourages research and development in the sector, leaving Africa dependent on the Global North. Overall, sub-Saharan Africa is home for 0.7% of the world's researchers and this rate could be even much lower in pharma research (UNESCO 2021b).

Brain drain is another issue that is lowering the availability of skilled and knowledge pharma expertise in Africa. Over 10% of sub-Saharan Africans with graduate degrees emigrate (the ratio is even more important in the pharma sector), seeking better research environments and working conditions (Simpkin 2019). More than a third of African trained scientists are living in developed countries (AUC 2012). One fifth of African born physicians work in high income countries (Mo Ibrahim Foundation 2021). Nigeria, for instance, lost about 9000 medical doctors to Canada, the United States and the United Kingdom between 2016 and 2018. Other countries of Angola, Malawi, Zambia, and Zimbabwe have had more than 50% of their doctors emigrate to other countries (Kigotho 2018). Developed countries offer attractive packages to expertise in science, technology, engineering and maths (STEM), e.g. for Green card for the US and the European blue card, which offers 1.2 times national average wage to experts in the medical fields, an attractive salary that they lack in their home countries especially Africa. Most African countries poorly remunerate their pharma expertise and rarely provide them with a clear career path in the pharma manufacturing sector causing higher staff turnover. As of 2018, despite having about 1.2 billion people, Africa had only 358,000 doctors, i.e. doctor ratio of 0.307 per 1000 people (Kigotho 2018).

Another impediment that is deterring the development of the pharma sector in Africa is the neglect of the local and traditional medical knowledge. 60% of people in SSA dwell in rural areas with no access to health care services and facilities and about 70% of these use African traditional medicines which have not been improved to meet

medical standards (Kasilo 2019; Atoki 2021). These have often relied on African traditional medicine, especially herbs to treat their health ailments. However, the quality, safety and efficacy of these traditional medical solutions remain unregulated and their potential therapeutic effects remain unknown. Colonial legacies have also left several biases towards traditional medicines, leaving it viewed as inferior to western medicine and neglected for further research (Ozioma and Nwamaka 2019). Africa also lacks the appropriate technology and formidable resources to invest in extensive research on traditional medicines in line with the WHO standards (Mothibe and Sibanda 2018). However, these medicines are always the last resort for Africans as they try to deal with the burden of diseases on the continent. This was the case during the COVID-19 pandemic, when the pandemic hit, some Africa countries took desperate measures approving herbal medicines (e.g. COVIDEX for Uganda; Covid-Organics for Madagascar and Tanzania; Zedupex for Kenya) as alternative treatments to the COVID-19 disease even when their efficacy and safety was refuted.

While African countries have made progress towards promoting the mutual recognition of qualifications of different countries (from the Arusha convention of 1981 to Addis convention of 2014, which entered into force in 2019) Shabani and Okebukola 2017; UNESCO 2021c), there are still issues which continue to hinder effectiveness of the existing policies in all African countries - whether it is at the national or the regional level. In ECOWAS, for instance, ministers of health emphasises that the lack of mutual recognition across borders continues to impede regional integrations (FIP 2020).

B. Recommendations

6.1 The EU should help address the pharma skills and labour shortage, and foster the development of a competent and knowledgeable pharma workforce that is able to respond to African health challenges.

The EU can support the existing and the development of pharma skills centres to upskill and reskill the regional workforce and facilitate knowledge sharing across different African countries. This initiative can benefit from already existing centres of excellence (CoE) at continental level (e.g. the AUDA-NEPAD CoE) and the regional CoEs (e.g. Bio-medical CoE). The EU could support these regional centres adopt the digital platforms to reach a maximum number of participants at regional level. This is the case of AUDA-NEPAD, which is already leading in mobilising support to design and establish an online learning platform (the Africa Pharma Learning Management system) to deliver online training and enhance individual and institutional capacity on health issues. The Africa Pharma Resource DataBase is another project AUDA-NEPAD is developing that is expected to provide a digital platform for investors, academia, and all interested stakeholders to interact (UNIDO 2021). The EU and other donors can utilise these platforms to better support digital learning, and ensure that they benefit any relevant individual irrespective of their gender.

Box 6: AfDB Centre of Excellence for Skills and Tertiary Education in Biomedical Sciences Project

The Centre of Excellence for Skills and Tertiary Education in Biomedical Sciences Project led by the AfDB aims to contribute to the development of a skilled workforce in biomedical sciences to meet East African Community (EAC) labour market needs and support the implementation of regional labour market protocols. It also supports the standardisation of medical qualifications across the region, in support of labour mobility. The Centre also supports the creation of a network of Centres of Excellence across East Africa, including a focus on nephrology and urology in Kenya, oncology in Uganda, cardiovascular health in Tanzania, and biomedical engineering and eHealth in Rwanda.

6.2 The EU should support the development skills observatories at the regional level to track and monitor the pharma skills needed in the regions, in order to identify skills-gaps, anticipate future needs - especially when linked to digitalisation, and development of upskilling/reskilling strategies.

The EU can support the development of regional skills observatories at the regional level to track and monitor the pharma skills supply and demand in the regions. Designing the relevant skills-policies and programmes targeting the pharma sector requires a solid understanding of the skills-supply and demand. This calls for assessing the skills-gap in given regions as a baseline to develop skills-development policies. Taking into account and monitoring meso and macro trends (e.g. the digitalisation of the pharma sector) is a complementary aspect to the skills gap assessment, which allows predicting skills' needs in the near future. A (pharma) skills observatory, positioned at the regional level, could help identify such gaps and meso/macro trends, based on a set of indicators agreed by member states (e.g. number of pharma graduates, specialisation, investment in lifelong training etc.). Positioning the Observatory at the regional level, would also help drawing complementarities between countries, in a way that fosters a flexible and skilled pharma workforce.

The EU could also fund feasibility studies and if successful, finance programmatic funding to implement the observatories. These observatories could accompany the PAVM envisaged regional capability and capacity centres. In addition, the EU, through the European Centre for the Development of Vocational Training (CEDEFOP), EMA but also its member states (see Box 7) could also share its own experience in coordinating skills development in the regional pharma sector.

Box 7: Learning from Luxembourg to create a Digital Skills Bridge

Luxembourg has adopted a digital skills bridge project that will aim at addressing the decline of demand for certain jobs and skills due to automation and digitalisation, and an increased demand for new jobs and skills that is currently not being met. This aims at identifying the existing skills gap through:

- identifying the future skills needed regarding their workforce;
- assessing current competencies of their employees that are affected by the aforementioned changes;
- identifying the best option for each affected employee, either on the internal or external labour market;
- training the new competencies according to the requirements of the identified future job.

This project also ensures that employers have counselling, planning and coaching and receive financial support for the cost of training depending on the targeted labour market and the salary cost of training (European Commission 2021).

6.3 The EU should support regional health research in the pharma sector, development and building of well-equipped medical laboratories as well as science centres for regulatory authorities and institutions of higher learning.

African governments should incentivise and provide better financial and non-financial packages to their medical and health science professionals. Given the current debt issue, governments have limited space to increase wages of pharma and health workers, but could find alternative ways to retain labour force (Karaki and Medinilla 2022). First, they can invest in health research and laboratory infrastructure - together with the support of the EU, as part of their endeavour to facilitate access to and transfer of technologies. This would offer interesting prospects for pharma and health students, who would be motivated to carry out research in their home country or the region, rather than migrating to Europe. The EU is also yet to establish a regional health research centre under the influence

of the Alliance for Biomedical Research in Europe, which has expressed a need for the European Council for Health Research that would promote Europe as a centre for health research innovation and promote coordination and long-term funding at the EU level. Similarly, Africa with the support of the EU and its member states could also invest in the establishment of an African health research centre that conduct research and development to generate new knowledge, facilitate adoption of new technology, which can be translated into new products and services that can address the continent's health problems in line with its Health Research and Innovation Strategy for 2018-2030 (AUDA-NEPAD 2019).

The EU is already among top funders of health research and development in Africa, however, most of these investments are directed to individual countries especially Universities. Investment in African regional health research and development is cost effective and allows the continent and REC health research centres to benefit from economies of scale (AfDB 2014). EU can coordinate with organisations such as WHO, GAVI, among others to support the region health centres with funding that is targeted on pharma research (basic and applied) and development to the centres of excellence (e.g. Bio-medical centres of excellence), to encourage innovation and inventors and improvements in the current pharmaceutical products on markets through reverse engineering. Health research will create a health competition, improve efficiency and affordability of pharma products. EU can also support AUDA-NEPAD CoEs to feature pharma research, provide room for the establishment of knowledge nodes and platforms for research, linking regional ambitions with member states national priorities and allowing for implementation of AU continental programmes, promoting knowledge sharing and partnerships.

6.4 The EU should support the adoption of favourable labour retention policies within the African continent.

For the brain drain problem to be addressed, there is a need to incentive and competitively remunerate the pharma and health workforce. This is partly the role of African governments but at the same time they have budget constraints which deter them from increasing the budget share for the health sector. At the same time, other medical workers whose education is sometimes funded by Africa national and regional initiatives migrate to offer their services to developed countries, Europe inclusive. For instance, more than 50% of doctors born in some African countries currently work in OECD countries which are predominantly European (OECD 2020). To support Africa, in return, the EU could give back at national and regional levels to close the health expertise gap that these professionals leave in their home countries. For instance, EU and its member states could offer incentives for their own students and workforce to work in Africa (or provide support to universities willing to create branches in Africa) and contribute more generally to knowledge - expertise exchange. Notably, the EU already provides educational funding to African students through scholarships both within Africa and in the EU. However, this support can be increased and extended to support regional pharma ambitions, helping increase the regional labour force in the sector and addressing the existing gaps created by brain drain through investing in training and development of new medical labour force, pharma inclusive.

6.5 The EU could support RECs in promoting labour migration policies and mutual recognition of qualifications within their regions, to allow for a more agile and flexible workforce.

Regional integration allows drawing on human resources more effectively and promoting growth through relevant upskilling - reskilling strategies, and effective labour migration and mutual recognition of professional qualifications (AfDB 2014). This helps explain why most RECs include skills development. The EU could support skills through a regional approach, by supporting the PAVM envisaged regional capability and capacity centres.

Labour migration and mutual recognition of qualifications policies can help address skills gaps by facilitating the free movement of pharma professionals within Africa. Beyond addressing skills gaps/shortage, these policies can also facilitate knowledge sharing between countries, and foster opportunities for cross-country collaboration. This is also an important issue that is part of the AfCFTA - as this may facilitate or prevent trade of services between countries. In fact, the AfCFTA obliges signatory countries to "*individually or through bilateral, multilateral or regional arrangements, mutually recognise academic, professional and technical qualifications of their nationals, and establish a continental qualifications framework*" (CDH 2021). In this context, the EU should support RECs in facilitating and enforcing recognition of qualifications of pharma and health professionals. A first step could be to support the development of a study led by African think tanks analysing the legal framework and its enforcement in practice, highlighting the political economy factors that prevent regional agreement to be implemented in practice. Further technical assistance support could be provided, tailored to the needs of the countries and regions.

6.6 The EU could support the exploitation of traditional medical knowledge and its development to address Africa health challenges while aligning with the international standards.

History shows that traditional African medicines have been revolutionised and developed to treat various health challenges, e.g. malaria, diabetes, among others but with little recognition of African traditional systems that have used these medicines for long (Wambebe 2018). Wambebe (2018) emphasises that if well researched and developed, African traditional medicine can provide lifesaving pharma solutions to not only African but global health problems through reverse pharmacology or clinical observational study. However, Africa needs extensive funding, technical capacity and advanced technology and equipment to research the therapeutic effects of traditional medicines, especially in regard to their usefulness in treating old and emerging health challenges (WHO 2013). This research could also further develop an understanding of traditional medicines and generate knowledge that can transform them into products that meet the needs of the current and future international health regulations.

The EU can also support the exploitation of local African traditional medical knowledge, further funding the establishment of (or existing) health science research centres that can study African traditional medicines which have been used to treat diseases long before orthodox medicines. Currently, about 34 research institutions from 24 countries in Africa have already taken on research in the use of ATM in dealing with existing diseases, e.g. HIV/AIDS, diabetes, hypertension within the WHO guidelines (Kasilo et. al 2019). RECs have gone ahead to establish pharmacopoeias (e.g. African herbal pharmacopoeia and West African herbal pharmacopoeia) to help in management of traditional medical knowledge. Partnering with international organisations like WHO, which are already supporting the development, recognition and integration of ATMs is essential. In 2020, regional experts from WHO, Africa CDC, and the African Union Commission for Social Affairs endorsed a protocol for phase III clinical trials of COVID-19 herbal medicines together with the establishment of the data and safety monitoring board for these trails (WHO 2020). The EU support towards leveraging of indigenous knowledge can help improve the development of advanced scientific knowledge whose benefits could be extended beyond the African region.

3.7. Health systems

A. Challenges

African governments spend limitedly on the health sector. Their health systems are underfunded, understaffed, underequipped and yet they are faced a considerable number of health challenges. Although Africa carries a larger burden of the world's diseases (23%) and has 16% of the world's population, it has less than 1% of the global financial resources and 3% of the health care workers (UN 2017). Most African countries have not yet achieved the Abuja declaration objectives of 2001, where they pledged to invest 15% of their annual budget towards improving the health sector. In 2011, six AU countries had achieved the Abuja declaration (Liberia, Madagascar, Malawi, Rwanda, Togo and Zambia) and a few others (e.g. Djibouti, Ethiopia, Lesotho and Swaziland) were close to reaching the set objective. However, these countries have not been consistent in their progress. In 2018, no country had met the 15% Abuja declaration pledge and some were spending less on the health sector than before (Mo Ibrahim Foundation 2021).

Poorly equipped health systems that provide no or limited access to essential medicines threaten the ability of African countries to address emerging health challenges and manufacture the necessary pharmaceutical products. At regional and national levels, health facilities lack essential medical products, equipment, technology, and infrastructure. These limitations were made more visible during the COVID-19 pandemic when Africa suffered great shortages of personal protective equipment, e.g. surgical masks, gloves, gowns and goggles (Tondel and Ahairwe 2020). As of May 2022, Africa had vaccinated only 17.4% of its population compared to 51.8% in Europe who had even taken the booster dose (Africa CDC 2022; Europe CDC 2022). The shortage of vaccines and overreliance on the Global North has left Africa health systems waiting on vaccine supplies that Western countries only care to provide after fulfilling their own local needs. Weak health systems also threaten the promise of regional production hubs as it is unlikely that countries that currently fail to meet the basic health financing would invest in providing the essential infrastructure and equipment for the newly established regional hubs.

African health systems face a shortage of healthcare workers. This shortage also undermined the continent's ability to better deal with the COVID-19 pandemic and threatens the continent's preparedness to deal with the future pandemics (Bradshaw, Temeselw Mamo and Akuagwuagwu 2022). The pandemic led to a high number of patients which overwhelmed the already weak health facilities. It also overstretched the healthcare labour force and its ability to ensure the treatment of COVID-19 and the vaccination rollout. Africa currently has the lowest health care worker to population ratio of 1.30 health workers per 1000 people which is below 4.5 health workers to 1000 people Sustainable Development Goals (SDGs) requirement (WHO 2017b). This shortage is expected to increase as the African population increases. By 2030, Africa will suffer the greatest shortage of healthcare workers globally, projected at 6.1 million (Mo Ibrahim Foundation 2021; Tulenko 2016). Inefficient health systems leave individuals to take on desperate options to deal with their health challenges as was observed during the pandemic.

The majority of the individuals in SSA lack health insurance services and it is estimated that 60% of individuals pay out-of-pocket (37% of Africa's health spending) to access health services (UN 2017; Ogbuoji et al. 2019). They incur high costs especially with the private sector, leaving them at the risk of falling back into poverty. When individuals cannot afford these costs, they are left with no choice but to forgo or delay (38%) medical care treatment (Ogbuoji et al. 2019). The burden of high costs is greater for women, who are already earning lower wages, involved in house care and also in the informal sector low paying jobs. Additionally, women face extra gender specific costs

associated with reproductive health. Unless this challenge is addressed, it threatens the ambitions of developing countries to achieve gender equality.

B. Recommendations

7.1 The EU could provide technical and financial budget support to increase public spending in the health sector, enabling African countries to effectively equip their health facilities with essential medical equipment, technology and well-trained workforce.

Functional health systems provide a foundation for successful regional health systems. Well-equipped health systems with a focus on health research are able to attract regional investors in the health sector and also host various regional health platforms (e.g. Rwanda, Senegal and South Africa as regional hubs also invest a relatively higher share of their budget in medical services). Investing in health systems, however, requires more than the political will and leadership. It requires a significant percentage of governmental resources, which several African governments may not have, especially with the effects of COVID-19 pandemic and the Russian invasion in Ukraine. Despite the renewed commitments to direct a significant share of the budget to health activities, most African countries are still unable to abide by their Abuja Declaration pledges.

The EU and its member states have been supporting several health projects and programmes in developing countries for several years, but could step up their efforts to support the investments of African countries in the health sector, paying particular attention to low-income and fragile countries. The EU has further expressed its ambition to support African health systems, that is "*...strengthening health systems and immunisation capacities of the African continent is at the centre of our work…*" (European Commission 2022). Strengthening health systems at national and regional levels allows detection and control disease outbreaks and guarding against future pandemics and endemics (WHO 2019b). With the ongoing global crisis, the EU can also take an opportunity to foster the use of special drawing rights (SDRs) to finance healthcare and health systems of low-income countries as already recommended by the IMF. This would allow African countries to have more liquidity reserves, additional concessional loans and potentially greater investment leverage in health systems.

7.2 The EU, should, through its development finance institutions support the private sector health MSMEs, to enable them to provide affordable health/pharma products and services and close the gaps left by the public sector.

The public sector cannot address all the health needs in Africa. There is a need to acknowledge the vital role of the private sector in closing the gap left by national health systems. According to IFC, Africa's health private sector has sometimes proven to be the only opportunity to promote health care access in the remote areas and poor urban slums which are usually neglected by the public sector (Atoki 2021). The European DFIs can support regional and national private health care initiatives that aim at providing health services to the vulnerable including low-income earners, women and children. They can do so through exploiting opportunities that are provided at the regional level by the Africa Health Fund and Investment Fund for Health in Africa and partnering with other international finance institutions such as IFC which are already investing in private health care in Africa (IFC 2019).

Additionally, following the pandemic, the DFIs pledged to support health systems in developing countries to bridge the investment gap by investing in promising health care providers especially those providing services to the most vulnerable communities (Gavas and Pleeck 2021). European DFIs indeed stepped up their investment in health systems of Africa during the COVID-19 pandemic, e.g. the EIB as the EU bank partnered with WHO to invest €500 million in African health systems, focusing on expanding the provision of essential health services, reducing the risk

of investing in health sector by the private sector, and promoting access to vaccines, diagnostics and medical products and services. However, this support is not enough to close the US$66 billion health financing gap in Africa (UNECA 2019). The EU through its DFIs, therefore, needs to direct more financial support towards health projects in SSA as opposed to the current concentration on energy (35.1%), transport (32.4%), and environment, water and sanitation (23.1%) (European Commission 2020). With the new EFSD+, the EU can target a certain share of financial support especially grants and concessional loans to the development of the private sector health care facilities. Strong national health systems will provide the essential building block for better regional health systems and improve the capacity of regional manufacturing hubs to take on the challenging innovative roles across all the value chain stages.

7.3 The EU should support the adoption of universal health insurance to help low-income earners especially women and the vulnerable to access healthcare services.

Africa needs to adopt a continental health insurance mandate that is well supported by the political will of regional and national leaders, and a proper political leadership to ensure its implementation. However, this requires a high budget to ensure that a large percentage of Africans who are economically vulnerable also get access to healthcare services. Countries such as Ghana and Rwanda have national health insurance plans to ensure that low income earners access health care services and products, whereas, others lack this scheme leaving the poor with no access to health care. The EU and its member states can step in to provide support, e.g. policy advice and funding, in this aspect. Some EU member states (e.g. the Netherlands) are already promoting health insurance for about 115000 Nigerians through its Health Insurance Fund (IFC 2010).

The EU health insurance support should also cover innovative digital solutions provided by the private sector to promote access to health services and products. This is the case of M-Tiba, which enables individuals to save and mobilise resources for their financial services including from donors (UN 2017). Such initiatives can be funded to go beyond the constraints of national borders and become regional platforms for accessing health care services. The EU can also partner with other international funders (e.g. WHO, IFC, BMGF, etc.) to support technologies that can improve service delivery, improve information accessibility and track adherence to regulatory requirements in remote and urban areas.

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HEAD OFFICE
SIÈGE
Onze Lieve Vrouweplein 21
6211 HE Maastricht
The Netherlands *Pays Bas*
Tel +31 (0)433 502 900

BRUSSELS OFFICE
BUREAU DE BRUXELLES
Avenue des Arts 44, 1000
Brussels *Bruxelles*
Belgium *Belgique*
Tel +32 (0)28 825 008

info@ecdpm.org
www.ecdpm.org
KvK 41077447