Report

The AfCFTA and the procurement of pharmaceuticals and vaccines

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October 2024

Supporting Investment and Trade in Africa (SITA)

How to cite: Abudu, D. and Ayele, Y. (2024) '*The AfCFTA and the procurement of pharmaceuticals and vacci*nes. ODI Report. London: ODI (https://odi.org/en/publications/the-afcfta-and-the-procurement-of-pharmaceuticals-and-vaccines)

Acknowledgements

This report has been prepared under the Supporting Investment and Trade in Africa (SITA) programme, an initiative funded by UK International Development from the UK government to support the negotiations and implementation of the African Continental Free Trade Area (AfCFTA). All views provided are those of the authors and not the responsibility of ODI, the AfCFTA Secretariat or the UK Government.

The authors would like to thank Mr Themba Khumalo and Kirti Narsai for their comments.

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Acronyms

AfCFTA	African Continental Free Trade Area
Afreximbank	African Export-Import Bank
Africa CDC	Africa Centres for Disease Control and Prevention
AIDS	Acquired Immune Deficiency Syndrome
AMA	African Medicines Agency
AMRH	African Medicines Regulatory Harmonization
API	active pharmaceutical ingredients
ARSO	African Organisation for Standardisation
AU	African Union
BADEA	Arab Bank for Economic Development in Africa
∆CC	change of chapter
∆CTH	change of tariff heading
∆CTSH	change of tariff sub-heading
CPPM	Centralised Pooled Procurement Mechanism
CTC	Change in Tariff Classification
EAC	East African Community
ECDS	Eastern Caribbean Drug Service
EU	European Union
GCC GPP	Gulf Cooperation Council Group Purchasing Program
GHG	greenhouse gas
GPO	group purchasing organisation
HIV	Human Immunodeficiency Virus
IPR	intellectual property rights
ITFC	International Islamic Trade Finance Corporation
MFN	most-favoured nation
OECS	Organisation of Eastern Caribbean States
PAHO	Pan American Health Organization
R&D	research and development
RoOs	rules of origin
SADC	Southern African Development Community
SP	Specific Production
SPPS	SADC Pooled Procurement of Pharmaceuticals Services
UNECA	United Nations Commission for Africa
UK	United Kingdom
US	United States
VA	Value Added
WITS	World Integrated Trade Solution

Executive summary

Prices of essential medicines are significantly higher in many African countries compared with the lowest international reference levels. One of the reasons for this is buyer fragmentation and lack of domestic pharmaceutical manufacturing capacity. Efforts are underway to coordinate the procurement of vaccines and other pharmaceutical products across the continent to capitalise on cost advantages. Simultaneously, there is a concerted effort to develop continental value chains within the pharmaceutical sector, encompassing multi-step production processes, including the sourcing of raw materials. The African Continental Free Trade Area (AfCFTA) can play a pivotal role in facilitating these endeavours, thereby contributing to the advancement of the pharmaceutical sector in Africa.

This report benefits from the collaboration with the Nelson Mandela School of Public Governance of the University of Cape Town aimed at developing a continental strategy for the development of the pharmaceutical industry under the AfCFTA (UCT-ODI, 2024). In this sense, both reports feed each other with information and insights.

The AfCFTA provides tariff-free access to African markets for firms that meet its rules of origin (RoOs). However, products that do not meet RoO criteria are subject to tariffs. Complying with RoOs incurs costs: firms must compare the preferential tariffs under the AfCFTA with the costs of compliance.

Our analysis indicates that the RoOs for pharmaceutical products are moderately restrictive. Additionally, African countries impose either zero or very low most-favoured nation (MFN) tariffs on pharmaceutical and vaccine products. Consequently, the preferential tariff benefits for firms meeting RoOs under the AfCFTA are minimal. Firms may opt to trade under MFN tariffs regardless of RoO restrictiveness, with positive implications for pooled procurement. Given these low tariff rates, the pooled procurement initiative may remain largely unaffected by RoOs. Waiving the RoO requirement for pharmaceutical and vaccine products could further simplify procurement.

Conversely, RoOs could influence initiatives to produce pharmaceutical and vaccine products within Africa. RoOs affect sourcing decisions for intermediate inputs and the development of regional value chains. Strict RoOs may encourage sourcing within the AfCFTA, whereas lenient RoOs may lead to sourcing from

outside the region, potentially hindering regional value chains. For vaccine ingredients and packaging, several African countries impose higher MFN tariffs, creating significant preferential margins if these inputs are sourced or produced within Africa. This incentivises pharmaceutical producers to source inputs within the AfCFTA and encourages non-African firms to relocate to Africa, fostering local pharmaceutical manufacturing and regional value chains. Balancing RoOs and tariffs are crucial to support pooled procurement initiatives and the development of local manufacturing in Africa. Therefore, a careful balance must be maintained in this context.

Furthermore, negotiating the relaxation of the current RoOs for pharmaceutical products in pooled procurement scenarios could allow for the importation of goods without strict adherence to RoO requirements, thus easing trade across borders. Moreover, it may be important to consider the implementation of self-certification for RoOs. Currently, RoO certification must be carried out by an approved exporter or a designated competent authority of the exporting state party. This process can be burdensome and time-consuming, particularly for small and medium-sized enterprises. Introducing self-certification, currently limited to consignments valued below $5,000, could substantially reduce the expenses linked with RoOs for traders.

Reducing tariffs and non-tariff barriers on imported critical pharmaceutical components like active pharmaceutical ingredients (APIs) will foster the cost-competitiveness of producers of critical final health products. Common external tariffs could be necessary to protect African producers and achieve the goal of boosting trade and economic integration. However, they may also hinder the growth of the pharmaceutical sector, given limited production capacity, particularly for APIs. Therefore, decreasing tariff barriers on imported essential pharmaceutical components like APIs could be economically advantageous in the short to medium term. This measure aims to support producers in attaining cost-competitiveness in manufacturing critical healthcare products.

Additionally, unnecessary technical barriers, in the form of non-tariff barriers such as non-coherent medicine regulations, weak medicine regulatory capacity and fragmentation of standards across countries, hampers pharmaceutical production and trade. To this end, the effectiveness and efficiency of the African Organisation for Standardisation (ARSO) and the African Medicines Regulatory Harmonization (AMRH) programme is crucial to creating a regulatory environment and guaranteeing standards to foster the advancement of the pharmaceutical industry. Specifically, rapidity and effectiveness in the adoption of standards and technical regulations ARSO is currently implementing as part of its Standards for Pharmaceutical and Medical Devices in Africa Project will

significantly support expanded production and intra-African trade in quality pharmaceutical products.

Adopting capacity-building measures will boost the technical capacity of procurement bodies and border management authorities. Improving the technical capacities of buyers or procurers will be crucial. Such capacities, especially those related to forecasting potential demand and assessing the health product needs of a particular demographic group or population, are vital. Capacity-building here will contribute to the timely procurement of health products, especially urgently needed ones like vaccines during times of health crisis. To enhance the efficiency of cross-border trade facilitated by pooled procurement, the technical capacities of personnel responsible for cross-border trade, crucially, border management authorities, should be improved.

1 Introduction

Access to essential pharmaceuticals and vaccines is crucial to public health in Africa, yet high costs often create barriers. One significant factor contributing to these elevated prices is the limited opportunity to negotiate effectively owing to decentralised purchasing and the absence of pooled procurement. This fragmentation leaves individual buyers, as price-takers, unable to secure a better deal. In contrast, pooled procurement allows multiple countries to combine their purchasing power, acting as a single economy of scale, or a larger buyer (a monopsony), which can leverage market influence to secure significant price reductions. This is particularly vital for Africa, where approximately 70–90% of medicines are imported and many countries have relatively small economies.

Efforts to establish pooled procurement mechanisms are gaining momentum at continental level. The African market for medicines and vaccines is about $50 billion annually, highlighting the potential for significant savings through coordinated procurement. Simultaneously, there is a concerted effort to develop continental value chains within the pharmaceutical sector, encompassing multi-step production processes, including the sourcing of raw materials. The African Continental Free Trade Area (AfCFTA) can play a pivotal role in facilitating these endeavours, contributing to the advancement of the pharmaceutical sector in Africa.

This study aims to assess how the AfCFTA can balance the facilitation of continental procurement of vaccines and pharmaceutical products with the development and integration of continental value chains. Specifically, it aims to provide evidence to support the AfCFTA Secretariat's engagement in policy discussions regarding the procurement of vaccines and pharmaceuticals. This will involve coordinating legal instruments and necessary exceptions to existing protocols, such as on rules of origin (RoOs), to facilitate the adoption and implementation of pooled procurement mechanisms. Ultimately, this research will assist the Office of the Secretary General in fulfilling this role.

The rest of the report is structured as follows. Section 2 provides an analysis of pharmaceutical and vaccine procurement initiatives at continental level. Section 3 assesses continental and AfCFTA policies and protocols. This includes an examination of intra-Africa and extra-Africa trade dynamics regarding pharmaceuticals, vaccines and related products. Additionally, we provide an evaluation of RoOs for pharmaceuticals and vaccines, along with an analysis of protocol

provisions concerning government procurement within the AfCFTA and the African Union (AU). We also consider the implications of these policies on procurement standards, harmonisation efforts across Africa and potential mutual recognition arrangements. Section 4 looks at crosscutting issues, focusing on poverty, climate and environment, and gender. Section 5 presents policy recommendations and Section 6 concludes.

2 Analysis of pharmaceutical and vaccine initiatives on continental procurement

2.1 Pooled pharmaceutical initiatives at continental level

Access to affordable pharmaceutical and vaccine products is crucial to public health, particularly for the most vulnerable. However, in many African countries, the prices of essential pharmaceutical products are significantly higher when compared with the lowest international reference levels (Dubois et al., 2021). Among a group of nine common molecules purchased by various low- and medium-income countries (including Senegal, South Africa, Tunisia and Zambia), Dubois et al. (2021) find that the mean price can vary by a factor of 16. Additionally, there is a price gap of up to 300% across various procurement channels within a single country.

One of the reasons for the higher prices of pharmaceutical and vaccine products, especially in Africa, is buyer fragmentation. The lack of pooled procurement limits the capacity to negotiate prices. In a decentralised purchasing system, the buyers are usually price-takers. Conversely, pooled procurement involves multiple countries combining their buying power. By acting as a single, larger buyer – a monopsony – pooled procurement can leverage its market influence to negotiate significant price reductions on essential medicines and vaccines. This is particularly critical for Africa, where approximately 70–90% of medicines are imported and many countries have small economies (Conway et al., 2019). These nations lack the purchasing power of larger economies, making it challenging for governments to secure favourable prices for essential medicines. Consequently, there are initiatives for pooled pharmaceutical and vaccine procurement at various levels, including continental, regional and national. The African market for medicines and vaccines is about $50 billion annually (Africa CDC, 2024).

At a continental level, significant initiatives are underway to establish an African pooled medicines procurement mechanism. This effort is spearheaded by the Africa Centres for Disease Control and

Prevention (Africa CDC) in collaboration with the African Export-Import Bank (Afreximbank), the United Nations Economic Commission for Africa (UNECA) and the AfCFTA (Fletcher, 2024). It aims to streamline the procurement process for vaccines, medicines and other health products across the continent. A major milestone was achieved in February 2024 when the pooled procurement strategy was officially formulated and agreed upon during the African AU Summit (Africa CDC, 2024). This follows from AU members' expansion of the mandate of the Africa CDC, which granted it authority over the manufacturing of medicines and diagnostics in addition to its responsibilities for vaccines (AU and UNECA, 2019).

The AfCFTA-Anchored Pharma Initiative, launched in November 2019, introduced the pilot Centralised Pooled Procurement Mechanism (CPPM). This initiative aims to enhance continental integration and improve health outcomes by increasing investment in the healthcare sector and expanding access to pharmaceutical products across Africa (UNECA, 2022). During its pilot phase, the CPPM plans to establish pooled procurement centres for specific maternal and reproductive pharmaceutical products in 10 targeted countries. Kenya and Ethiopia will serve as anchor source markets for Comoros, Djibouti, Eritrea, Madagascar, Mauritius, Rwanda, Seychelles and Sudan (ibid.).

The initial phase of the CPPM focuses on establishing an institutional framework, securing government support and engaging partners. The second phase involves coordinating information-sharing and ensuring transparency through platforms for exchange, joint market analyses and enhancing product quality while reducing costs. In the third phase, the emphasis shifts to group contracts and consolidating demand, achieved by sharing data to unite demand across countries and negotiating group contracts for better pricing. The final phase aims to establish a dedicated agency for regional pooled procurement, with clear governance structures and expertise essential for centralised procurement and supply management.

A significant step towards pooled procurement in Africa is the harmonisation of standards. The Treaty for the Establishment of the African Medicines Agency (AMA) was signed on 11 February 2019 and came into force on 5 November 2021, following the deposit of the 15th instrument of ratification (AU, 2019). The AMA, building on the African Medicines Regulatory Harmonization (AMRH) programme, seeks to coordinate and harmonise medicine regulation across the continent. With 27 countries having ratified the AMA Treaty to date, and more expected to follow, the creation of the AMA aims to foster collaboration among African countries and regions, creating a more unified regulatory market. This harmonisation is a crucial step for the success of pooled procurement initiatives.

2.2 Modes of pooled procurement

There are various modes of pooled procurement, as Figure 1 illustrates. The degree of coordination in each mode ranges from low to high, and different activities and organisational arrangements are involved. The most basic arrangement, with a low degree of coordination, is the information-sharing model. In this, countries exchange data on pricing, vendor performance, suppliers and products. However, each country still manages its own procurement processes independently. The next level is coordinated informed buying. Here, countries conduct joint market research, share information on supplier performance and monitor prices together. Despite this collaborative effort, each country makes its own purchasing decisions. The third model is group contracting. Under this arrangement, countries unite to negotiate product pricing as a single entity, securing a more favourable price structure. Individual nations then handle their own procurement using the collectively negotiated prices. The fourth arrangement is central contracting and purchasing. In this model, a central management agency acts on behalf of all participating countries, conducting joint tendering, awarding contracts and managing purchases. The final and most integrated model is the group purchasing and distribution model. This involves a centralised distribution organisation that combines group purchasing with supply chain management, creating a fully integrated supply chain operation (UNECA, 2023a).

Figure 1 Modes of pooled procurement

Source: Adapted from Espin et al. (2016) and Nemzoff et al. (2019)

2.3 Regional bloc pooled procurement experiences

There are also initiatives and experiences from regional blocs in Africa regarding pooled drug procurement mechanisms.

2.3.1 Southern African Development Community

SADC Pooled Procurement of Pharmaceuticals Services (SPPS) aims to address the challenge of acquiring essential medicines and medical supplies.[1] By consolidating the purchasing power of member states, it improves affordability and access to these critical resources (SADC, 2018). It began in November 2011, when SADC Health Ministers approved the SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013–2017 (SADC, 2011). The SPPS procurement process begins with member states identifying their needs. A tender is then issued and a price catalogue shared, allowing member states to select items for purchase and submit their orders. A supply plan is then created, informing member states about total savings and delivery schedules (SADC, 2018).

The programme has delivered benefits. By September 2018, SADC had signed contracts with 122 manufacturers of pharmaceutical and medical supplies. SADC has achieved price reductions of 15–80% on medicines procured through SPPS, with an average saving of 40%.

However, challenges persist. Economic disparities among SADC members can affect their commitment and ability to participate fully. Overlapping memberships with other regional economic blocs can complicate the establishment of a unified legal framework for pharmaceutical procurement. Additionally, some member states, particularly least-developed countries, may be eligible for even lower prices on generic drugs through the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (Government of Botswana, 2021).

2.3.2 East African Community

In 2008, the EAC approved a regional bulk procurement model. This pooled procurement approach relies on information-sharing and coordinated informed buying, facilitated by the EAC and other trade agreements. Funding for procurement typically comes from individual countries or donor contributions, with no centralised funding mechanism. While the principles and concept of pooled procurement have yet to be fully implemented, efforts are ongoing to harmonise and improve the policy and regulatory environment for procurement among EAC member states.[2]

Other than African, there are also other initiatives and experiences.

[1] See www.msd.go.tz/sadc-pooled-procurement
[2] See www.epnetwork.org/pooled-procurement/

2.3.3 Gulf Cooperation Council Group Purchasing Program

The GCC GPP, initiated in 1997 among seven Persian Gulf states (with Yemen joining in 2004), jointly issues tenders for vaccines, drugs and medical goods. This programme addresses the challenge of high prices and the difficulty of procuring the small quantities that countries require. The pooled procurement model is a ‘group contracting’ programme whereby countries independently contract with and pay producers once the group has selected the winning bids. The programme has issued 10 tenders involving nearly 8,900 different products valued at $508 million in 2003 and has been increasing. It has successfully cut costs and ensured a consistent and sufficient supply of vaccines for member countries.

2.3.4 Pan American Health Organization

The PAHO Revolving Fund was established in 1979 to enhance immunisation programmes across the Americas. It procures supplies on behalf of more than 35 countries in Latin America and the Caribbean. The pooled procurement model is the ‘central contracting' model, which manages most aspects of procurement, from tendering to contracting with and paying producers. It uses a common fund to compensate producers before reimbursement by countries upon receipt of goods. The programme has successfully reduced costs and ensured a consistent supply of medicines.

2.3.5 Organisation of Eastern Caribbean States

The OECS established the Eastern Caribbean Drug Service (ECDS) in the late 1980s, comprising nine small island nations. The ECDS procures pharmaceuticals and medical supplies for the nine ministries of health of the OECS countries. It uses a centralised contractual purchasing model. The ECDS operates a centralised, restricted tendering system, pre-qualifying all approved suppliers through a registration questionnaire. It solicits bids from international suppliers, awards annual contracts, places orders directly with suppliers and monitors delivery and supplier performance.

Parmaksiz et al. (2022) conducted a systematic review of various studies on the pooled procurement of medicines and vaccines to identify the key elements of success. They identified several essential factors necessary for the effective functioning of pooled procurement mechanisms. First, for participation in pooled procurement, buyers require adequate levels of technical and financial capacity, and compatible laws and regulations. Second, for the execution of pooled procurement, the organisation must possess sufficient financial and technical expertise, and operate independently. Third, to ensure the provision of health commodities to the mechanism, suppliers need adequate incentives, such as a sufficiently large market size and a prompt payment mechanism.

3 Assessment of continental and AfCFTA policies and protocols

3.1 Trade within Africa and with the rest of the world in critical products

Africa relies heavily on imports of pharmaceutical and vaccine products from the rest of the world. Figure 1 shows the dynamics of extra-Africa exports and imports in pharmaceuticals and vaccine products as well as critical vaccine inputs. Over the past decade, there has been a consistent increase in these imports. In 2021, Africa imported a substantial $17 billion worth of pharmaceutical products from outside the continent, a significant rise from $6.6 billion in 2017. The surge in vaccine imports in 2021 was driven significantly by the COVID-19 pandemic. Conversely, Africa's exports to the rest of the world amounted to only $0.9 billion in the same year. This results in a considerable trade deficit in pharmaceutical products and vaccines. This deficit has been on the rise over the past two decades.

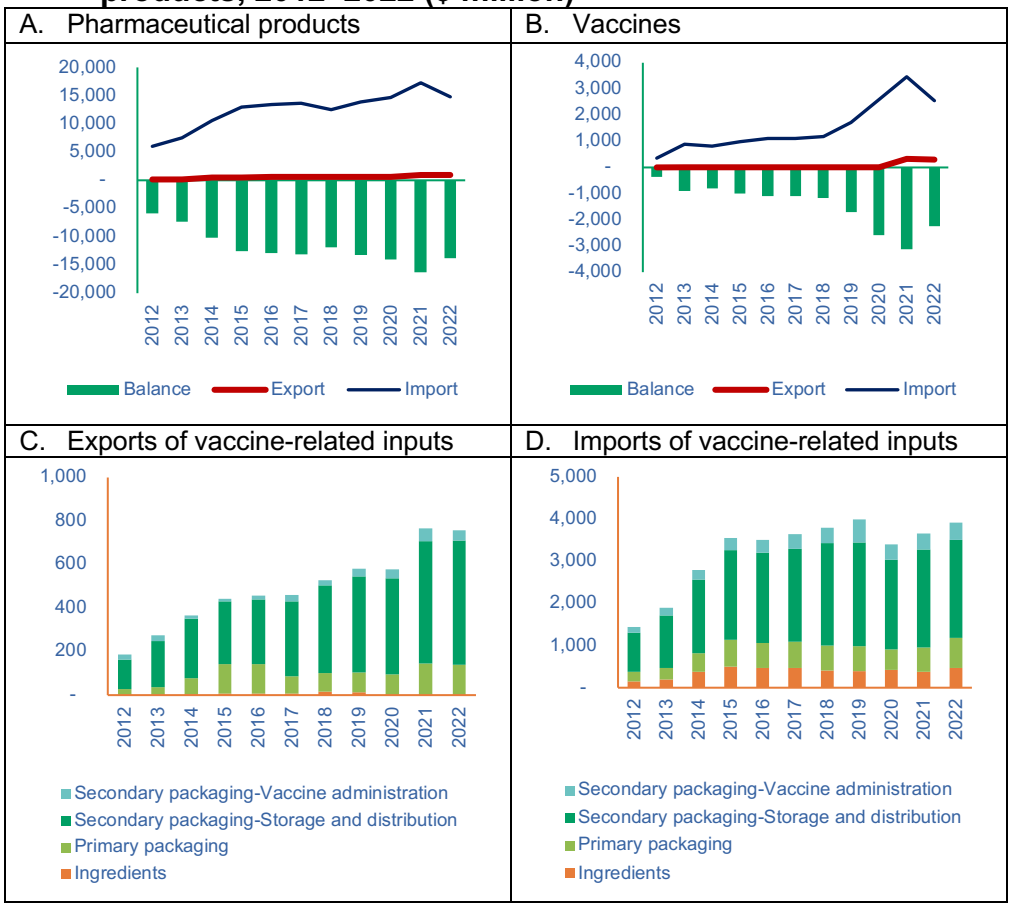
Figures 2C and 2D show imports and exports of vaccine-related inputs by category from the rest of the world.[3] Most of the imports consist primarily of packaging materials rather than ingredients for further processing. The majority of vaccine-related inputs in exports and imports pertain to secondary packaging for vaccine administration and packaging materials for storage and distribution.

India is Africa's main source of imports for pharmaceutical products (Figure 3). In 2022, African imports from India were at $3 billion, covering 21% of the continent's total imports. This was followed by imports from France, at $1.2 billion (11%) and from Germany and the US, each at $1.2 billion (8%). These four countries account for close to 50% of Africa's pharmaceutical imports. Except for in India, almost all imports are mainly from advanced countries' economies such as the EU and the US.

Belgium and the US are the main sources of vaccine imports for Africa, each covering 28% and 16% of vaccine imports in 2022.

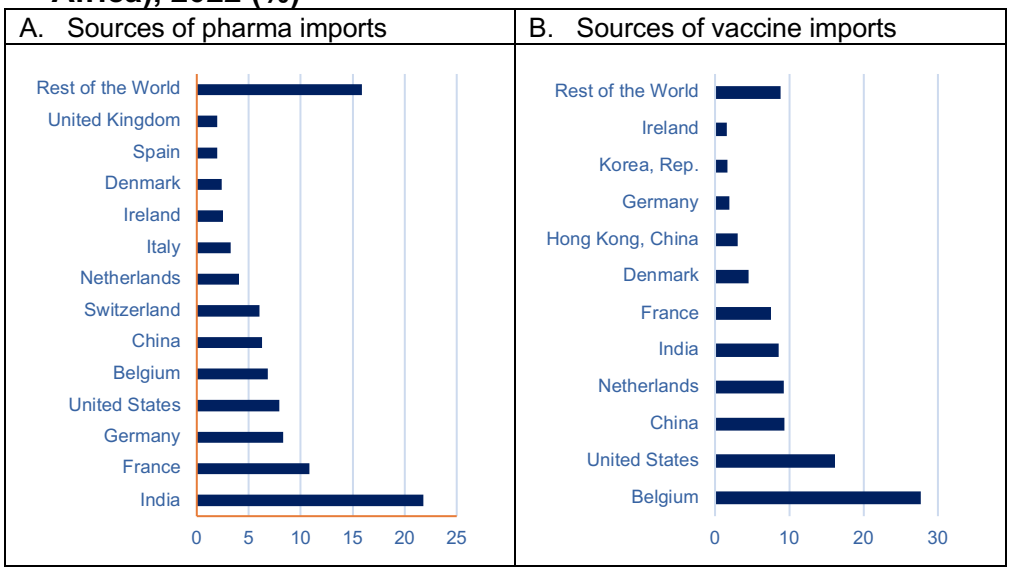
[3] See Appendix 1 for the list of selected vaccine-related inputs considered in this study.

Figure 2 Extra-Africa trade in pharmaceutical and vaccine products, 2012–2022 ($ million)



Source: Authors' elaboration from WITS database

Figure 3 Sources of imports for pharma products (extra-Africa), 2022 (%)

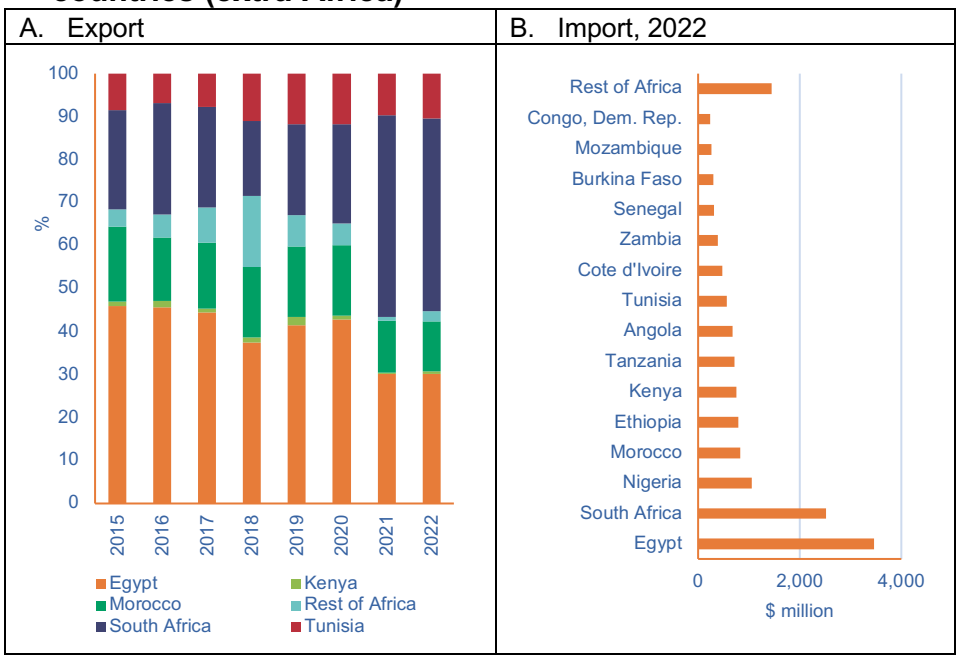


Source: Authors' elaboration using (2022) data from the WITS database

Figure 4 shows extra-Africa pharmaceutical and vaccine product exports and imports by individual African countries. It shows that South Africa and Egypt are the predominant exporters of pharmaceutical and vaccine products from Africa to the rest of the world (extra-Africa exports). These two nations alone accounted for over 75% of Africa's exports in 2022. Over 2015–2022, they collectively represented more than two-thirds of the continent's exports globally. Specifically, in 2022, South Africa exported pharmaceutical products totalling $420 million, while Egypt exported $283 million worth of products to international markets.

Both Egypt and South Africa are also the two largest importers of pharmaceutical products within the continent. Egypt imported products valued at $3.5 billion, while South Africa imported goods worth $2.5 billion. Following closely behind as top importers are Nigeria ($1.1 billion), Morocco, and Ethiopia (each at $0.8 billion).

Figure 4 Africa pharmaceutical exporters and importers countries (extra-Africa)



Source: Authors' elaboration from WITS database

3.1.1 Intra-Africa pharma and vaccine trade

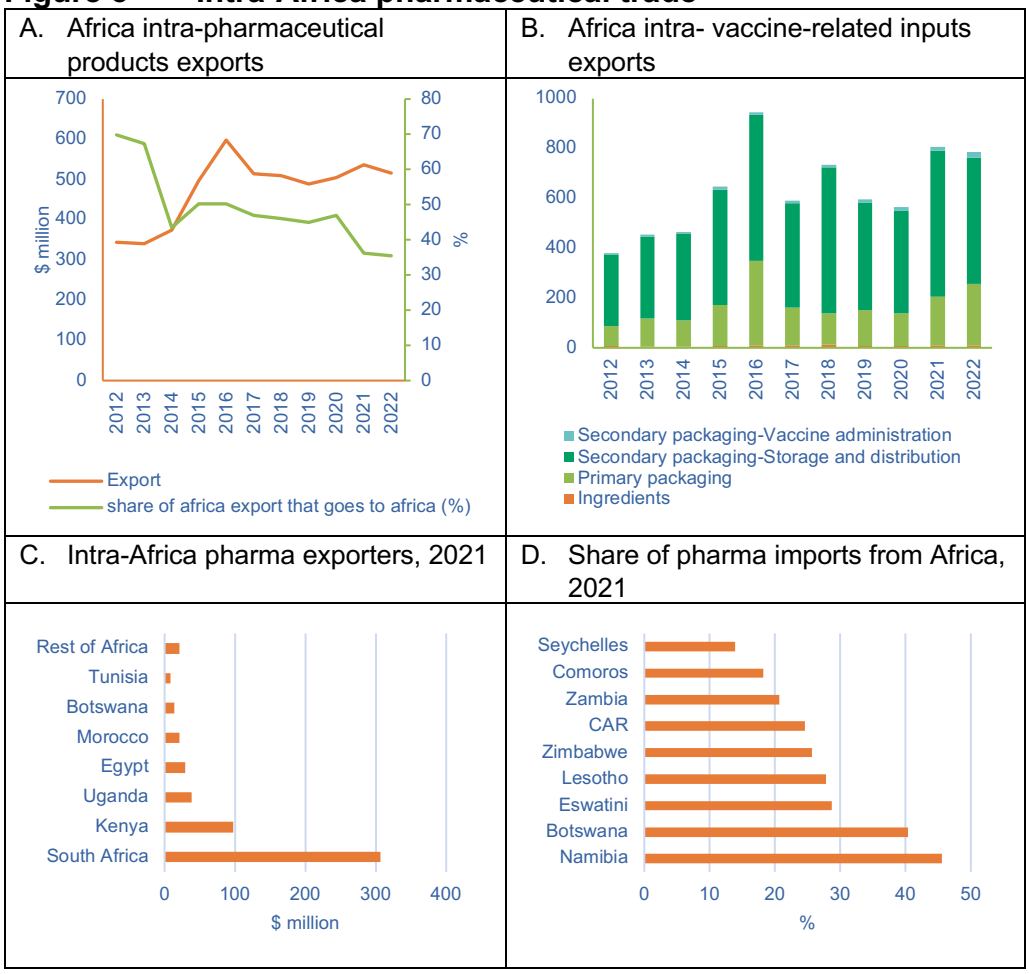
The intra-Africa pharmaceutical and vaccine trade is not significant. For instance, in 2021, the intra-Africa trade of pharmaceutical products amounted to $536 million; vaccine trade was smaller, at $51 million, in the same period. A significant portion of pharmaceutical products is exported within the continent. For instance, in 2021, approximately 35% of Africa's global exports were traded within Africa. However, this is a decline in 2012, when more than 70% of pharmaceutical Africa's exports were intra-continental.

Regarding vaccine-related inputs in intra-Africa trade, Figure 5 illustrates that a substantial share of intra-Africa exports is related to

packaging and vaccine administration products, while trade in ingredients remains minimal. In 2021, total exports in intra-Africa trade amounted to $807 million. However, only $11 million of this constituted ingredients, with the remainder comprising primary and secondary packaging and vaccine administration products.

Intra-Africa pharmaceutical exports are driven predominantly by a few countries. South Africa leads, with exports totalling $307 million, comprising 57% of the total intra-Africa pharmaceutical trade. Kenya follows with $98 million, accounting for 18%. Although Egypt is a major exporter of pharmaceutical products globally from Africa, its share of exports to Africa stands at just 5%.

Figure 5 Intra-Africa pharmaceutical trade



Source: Authors' elaboration from WITS database

In terms of critical vaccine-related inputs in intra-Africa exports, South Africa maintains its leading position, with exports valued at $291 million. Rwanda and Morocco follow, with $88 million and $84 million, respectively. Tunisia and Egypt emerge as major exporters of vaccine-related inputs; however, the majority of their exports are directed outside of Africa rather than within.

A handful of countries import a portion of their total pharmaceutical products from Africa. Namibia has 46% of its imports originating from

Africa; Botswana follows closely with 40%. Eswatini and Lesotho import 29% and 28% of their total pharmaceutical products from Africa, respectively, with Zimbabwe close behind at 26%. These countries are located in Southern Africa.

3.1.2 Tariffs

Several countries in Africa impose tariffs on imported pharmaceutical products. Table 1 reports the average applied most-favoured-nation (MFN) tariff on pharmaceutical products and inputs for 2021. Twenty African countries maintain a zero-applied MFN tariff. The rest impose tariffs. Morocco has the highest tariffs, at 12.9%, followed by Algeria at 4.9% and Ethiopia at 4.2%.

Table 1 Pharmaceutical product tariffs

Country	Pharma	Vaccine	Vaccine-related inputs			
			Ingredients	Primary packaging	Secondary packaging – storage and distribution	Secondary packaging – vaccine administration
Algeria	4.9	2.5	15.0	22.5	21.0	21.7
Angola	0.5	0.0	0.0	13.0	35.0	0.0
Benin	0.0	0.0	5.0	10.0	12.4	5.0
Botswana	0.3	0.0	0.0	7.4	9.7	5.0
Burkina Faso	0.0	0.0	5.0	10.0	12.4	5.0
Burundi	0.6	0.0	1.7	17.5	18.1	0.0
Cape Verde	0.7	0.0	0.0	7.5	3.1	0.0
Comoros	0.0	0.0	20.0	12.5	9.2	0.0
Côte d'Ivoire	0.0	0.0	5.0	10.0	12.4	5.0
Eswatini	0.3	0.0	0.0	7.4	9.7	5.0
Ethiopia	4.2	0.0	10.4	25.0	12.2	5.0
Gambia, The	0.0	0.0	5.0	10.0	12.4	5.0
Ghana	0.0	0.0	5.0	10.0	12.4	5.0
Guinea	0.0	0.0	5.0	10.0	12.4	5.0
Guinea-Bissau	0.0	0.0	5.0	10.0	12.4	5.0
Kenya	0.6	0.0	1.7	17.5	18.3	0.0
Lesotho	0.3	0.0	0.0	7.4	9.7	5.0
Liberia	0.0	0.0	5.0	10.0	12.4	5.0
Libya	0.1	0.0	5.0	5.0	3.9	0.0
Madagascar	0.0	0.0	4.2	14.4	7.6	0.0
Malawi	0.2	0.0	0.0	17.5	13.8	0.0
Mali	0.0	0.0	5.0	10.0	12.4	5.0
Mauritania	0.0	0.0	5.0	10.0	11.2	5.0
Mauritius	0.0	0.0	0.0	0.0	0.4	0.0
Morocco	12.9	10.0	9.4	29.2	17.4	2.5
Mozambique	0.0	0.0	1.7	13.8	10.0	5.0
Namibia	0.3	0.0	0.0	7.4	9.7	5.0
Niger	0.0	0.0	5.0	10.0	12.4	5.0
Nigeria	0.0	0.0	5.0	10.0	12.4	5.0
Rwanda	0.6	0.0	1.7	17.5	18.1	0.0
Senegal	0.0	0.0	5.0	10.0	12.4	5.0
Seychelles	0.0	0.0	0.0	5.0	0.0	0.0
Sierra Leone	0.0	0.0	5.0	10.0	12.4	5.0
South Africa	0.3	0.0	0.0	7.4	9.7	5.0
Tanzania	0.6	0.0	1.7	17.5	18.1	0.0
Togo	0.0	0.0	5.0	10.0	12.4	5.0
Uganda	0.6	0.0	1.7	17.5	20.0	0.0
Zambia	0.3	0.0	5.4	13.5	18.8	0.0
Zimbabwe	3.8	0.0	4.2	16.9	29.6	2.5

Source: Authors' elaboration from WITS database

3.2 Rules of origin on pharmaceuticals and vaccines

The AfCFTA provides tariff-free access to Africa's markets provided firms meet the RoOs outlined in the Agreement. The aim of the RoOs

is to provide preferential tariff benefits exclusively to AfCFTA member nations while preventing trade diversion from non-member countries. Consequently, products failing to meet RoO requirements are subject to tariffs.

However, challenges arise in the context of the initiative on pooled procurement for pharmaceutical products at the continental level. Pharmaceutical products may be procured either within Africa or from outside the continent. If the pooled procurement is from manufacturers and products produced within Africa and all meet RoO requirements, this does not pose an issue for the pharmaceutical initiative. Implementation of the AfCFTA will facilitate this process.

However, it is improbable that all pharmaceutical and vaccine production within Africa will meet the RoOs outlined in the Agreement. This is primarily because of the global nature of pharmaceutical and vaccine production, which relies on multiple ingredients and value chains spanning across the globe.

Also, Africa imports a significant portion of its pharmaceuticals and vaccines from outside Africa. If pharmaceutical products are procured from outside Africa as part of pooled procurement, they do not meet RoO requirements and are thus subject to tariffs. In addition, in 2022, over 20 African countries still impose tariffs on pharmaceutical products.

This highlights how RoO origin requirements for pooled procurement of pharmaceutical products can have significant impacts on trade, especially in scenarios involving inter-country trade. The extent of this impact varies based on the chosen procurement mode. Stringent and costly RoOs have the potential to hinder trade in pharmaceutical products among African countries, thereby affecting regional pharmaceutical and vaccine procurement initiatives.

3.2.1 Rules of origin for pharmaceuticals under the AfCFTA

Under the AfCFTA, product-specific RoOs are set at the 6-digit HS code level. For pharmaceutical products, the RoOs stipulate ‘Manufacture from Materials of any Heading, except that of the Product or Manufacture in which the value of the Materials used does not exceed 60% of the ex-works price of the Product or Chemical processing rules as per Introductory Note 8 to this Appendix.’ This implies that traders or firms have the option to choose between Change in Tariff Classification (CTC), Value Added (VA) or Specific Production Process (SP) to comply with the rules. In other words, there must be a sufficient production process to claim origin. These rules apply to all pharmaceutical products in the AfCFTA.

The CTC rule requires substantial transformation in production leading to a change in tariff classification from non-originating materials used when exported as a final product. The VA rule sets a limit on the maximum non-originating value that can be used for an

exported product. Under this rule, the maximum value of non-originating materials is defined. The SP rule grants originating status to a good if it has undergone a specific production process, specifying a set of production processes necessary for a good to be considered originating.

The challenge for firms in meeting RoOs for pharmaceutical products varies depending on the specific firm and product. However, existing literature, including works by Estevadeordal (2000), Anson et al. (2005) and Cadot et al. (2006), indicates that RoOs based on changes of chapter (∆CC) are more stringent compared with those based on changes of heading (∆CTH), which, in turn, are more restrictive than rules based on changes of subheading (∆CTSH). Currently, one of the criteria for meeting RoOs is a change in heading. Additionally, the VA requirements, where the value of materials used should not exceed 60% of the ex-works price of the product, signify that a significant portion of the value added in the manufacturing process originates from within the country or region where the product is claimed to be manufactured. The difficulty level in complying with the SP rule can vary significantly across industries but it specifies a set of production or chemical processes sufficient for the product to be considered origin. In summary, these rules indicate that meeting RoO requirements for firms is not easy.

In addition to product-specific RoOs, there are also regime-wide RoOs, which are applied to all goods traded under the AfCFTA. These are not specific to any product. Some of these regime-wide RoOs offer flexibility to the product-specific RoOs, including de minimis (or tolerance) and cumulation. The de minimis rule provides leniency in RoOs by permitting the use of a small percentage of non-originating materials in production. This means that, even if a product does not meet the product-specific RoO criteria for preferential tariff treatment, it may still qualify as originating under the broader de minimis RoO criteria. The cumulation rule allows producers within a free trade area to utilise inputs from other member countries without losing the preferential status of the final product. In bilateral cumulation, an originating input from one country retains its origin status when used in another country's production process. In diagonal cumulation, originating inputs from each member country are considered to originate from inputs in other member countries. The AfCFTA allows diagonal cumulation, treating all African countries as a single territory for origin determination. Consequently, any product that has obtained origin status in any part of the area covered by the AfCFTA will be deemed as originating in another country when used as an input in producing another product. These rules provide support for initiatives such as pooled procurement.

3.2.2 Possible actions to support continental-level procurement

One possible solution to support the pooled procurement initiative under the AfCFTA arrangement is the option to negotiate relaxation of the current RoOs for pharmaceutical products in pooled procurement scenarios or outline alternative RoOs origin or procedures for determining eligibility for tariff preferences. This may permit the importation of products without the need to strictly meet the usual RoO requirements, facilitating trade across borders.

3.3 Protocol provisions in relation to rules and procedures in the AfCFTA

The AfCFTA has protocols that can facilitate increased production, trade and investment, which could contribute to economic development. This is because, as for other priority industries of the AfCFTA, the provisions and objectives of these protocols seek to support the development of a robust pharmaceutical industry. Expanding the pharmaceutical industry will be crucial as Africa has a high disease burden and limited access to medicines and is still highly import-dependent for its pharmaceuticals. Thus, if successfully implemented, the protocols can bolster access to affordable, high-quality, efficacious pharmaceutical products.

3.3.1 AfCFTA protocols for trade in goods and services

The AfCFTA protocols for trade in goods and services were negotiated in the initial stages (phase I) of the Agreement, with discussions centred on areas like tariff schedules and RoOs and services such as transportation and business services.

As detailed in Article 3 of the AfCFTA Agreement, the protocols advocate for the gradual removal of tariff and non-tariff barriers, paving the way for a liberalised product market. Thus, they can bolster intra-African trade in pharmaceuticals. Creating a substantial regional market has the power to attract more manufacturers, thereby expanding the size of Africa's pharmaceutical industry.

To put things in context, the market size of Africa's pharmaceutical industry, gauged as the value of the industry, was estimated to be between $40 billion and $60 billion in 2020, which is pale compared with those of the US (estimated value of $393 billion) and Japan ($123 billion) (McKinsey & Company, 2015). The small size of Africa's pharmaceutical industry, even though the continent bears significant shares of the world's communicable and non-communicable disease burdens (Narayan, 2016; Bigna and Noubiap, 2019), owes to the small number of pharmaceutical companies. More specifically, in 2020, Africa had 600 pharmaceutical manufacturers, much lower than the number in India (20,500) and China (5,000), which have populations similar in size to that of Africa (Conway et al., 2019; Ussai et al., 2022).

Hence, effective use of the protocols for goods and services can be critical for increasing the size of manufacturing capacity and making

it more capable of increasing access to affordable, high-quality and efficacious pharmaceutical products. Studies (Sidibé et al., 2014; Lakdawalla, 2018; Bennett and Yin, 2019) show that economies of scale, contributing to cost reduction and higher quality of pharmaceutical products, are associated with producing for larger markets.

3.3.2 Protocol on rules and procedures on the settlement of disputes

The AfCFTA recognises the need for a framework of rules and procedures for dispute resolution associated with issues, including the trade and procurement of pharmaceutical products. The main objective is to ensure that the framework established for dispute resolution is transparent, fair, accountable, and predictable, according to the provisions of the AfCFTA Agreement.

The efficacy of procurement in expanding the market for African-manufactured pharmaceuticals will depend mainly on the rules and regulations regarding dispute resolution associated with procurement. These can strengthen trust and cooperation between producers and buyers on the continent, especially in pooled procurement mechanisms.

However, the current form of this protocol is effective only for resolving inter-state disputes, as it is not accessible to the private sector or individuals. Thus, since the private sector will be salient for the effectiveness of pooled procurement, this protocol will need to be made accessible to the private sector to enhance its effectiveness by strengthening trust and cooperation between buyers and sellers. Additional support to this argument is that existing dispute settlement mechanisms in Africa tend to have more cases when accessible to the private sector, as in the Economic Community of West African States and the EAC (Tsighe, 2019).

3.3.3 Protocols on investment, intellectual property rights and competition policy

To increase the local supply of pharmaceuticals, more intra-African investment underpinned by a better investment environment, providing a climate for fair competition, will be required. The AfCFTA protocols on investment, intellectual property rights and competition were created for this purpose. These were negotiated in phase II of the Agreement and adopted on 19 February 2023 by the AU Assembly of Heads of State and Government (UNECA, 2023b).

The protocol on investment aims to facilitate intra-African investment with transparent and predictable legal provisions to guide flows and settle disputes. Increasing intra-African investment in the pharmaceutical sector will be critical to spreading the economic benefits (e.g., creating jobs and increasing foreign exchange

earnings) associated with the industry and reducing regional inequality in access to high-quality, affordable pharmaceuticals.

A study of 400 pharmaceutical companies in Africa in 2021 found that contrary to historical trends, where foreign subsidiaries and multinationals dominated the pharmaceutical manufacturing landscape, African-owned companies made up 50% of the total (Development Reimagined, 2022). Nonetheless, more foreign investment and partnering with African manufacturers will be required to expand the industry. This will be critical for the supply of active pharmaceutical ingredients (APIs), which are still acutely limited on the continent but are crucial for the cost-competitiveness of pharmaceuticals and other high-value pharmaceutical products. A notable positive example of African–foreign partnership is the recent trial of R21 in Ghana, Kenya and Malawi to produce a local malaria vaccine following a World Health Organization-recommended rollout of GlaxoSmithKline's Mosquirix malaria vaccine (Nakkazi, 2021).

Legal provisions underlying intellectual property rights (IPR) are fragmented in Africa. Thus, the AfCFTA protocol on IPR seeks to harmonise rules and principles on promoting, protecting and enforcing such rights to foster innovation in products, including pharmaceuticals, on the continent. A recent study analysing patent data from the African Regional Intellectual Property Organization and the Organisation Africaine de la Propriété Intellectuelle shows that African patent activity is low, with most patents covering HIV/AIDS (Motari et al., 2021). The findings hint at the need to improve Africa's health innovation system, which could be critical in leveraging opportunities availed through the IPR protocol of the AfCFTA. An area in the pharmaceutical value chain where harmonised IPR may be relevant is pharmaceutical research and development (R&D), essential for the sector's innovativeness to facilitate the consistent production of affordable, high-quality products.

The competition protocol aims to attenuate anti-competitive behaviour in the marketplace. Anti-competitive behaviour by incumbent pharmaceutical manufacturers can be detrimental to the entry of new players, which is essential to fostering the competition needed to produce price-competitive pharmaceutical products.

3.4 Pharmaceuticals standards, their harmonisation and/or mutual recognition arrangements

Harmonisation of standards will be vital for the AfCFTA to effectively support the expansion of trade and the development of a robust pharmaceutical industry. This is mainly because harmonisation of standards can guarantee the quality of pharmaceutical products, enhancing demand and, consequently, intra-regional trade. Additionally, harmonising standards can be crucial to combat illicit trade and the production and trade of substandard and falsified pharmaceutical products.

The potential crucial role of standard harmonisation has not gone unnoticed by policymakers; indeed, it has been recognised and acted upon. Accordingly, apart from the Arab Maghreb Union and the Economic Community of Central African States, all regional economic communities have taken steps to harmonise standards and coordinate quality policies (UNECA, 2020). These regional standards have some gaps and are not coordinated at the continental level to support the AfCFTA's objective of contributing to the expansion of production and intra-African trade of products, including pharmaceuticals. In particular, the fragmentation of standards serves as a technical barrier to intra-regional trade, an issue that provisions of the AfCFTA through Annexes 6 and 7 seek to attenuate.

To this end, ARSO, the continent's intergovernmental standards body, has been mandated to generate tools for developing and harmonising standards, assessing their conformity and facilitating the effective implementation of standards mechanisms. More specifically, the AfCFTA Technical Barriers to Trade Annex 6 requires state parties to (i) develop and adopt international standards, (ii) promote adopting standards developed by ARSO, and (iii) utilise ARSO's standards for trade where a similar international standard does not exist.

Following the AfCFTA Secretariat's recognition of the pharmaceutical industry as part of four priority value chains, as captured in its Private Sector Development Strategy 2022–2023, ARSO has expanded its mandate to harmonise the standards and technical regulations of the pharmaceutical industry. In particular, a partnership between Afreximbank, the International Islamic Trade Finance Corporation (ITFC), the Arab Bank for Economic Development in Africa (BADEA) and ARSO was set up in 2020 to achieve this objective and reflect AfCFTA priorities. To this end, the AfCFTA Secretariat ARSO Implementation Plan 2022–2025 was created (Kithome, 2022).

Implementation of the project has resulted in harmonising 113 standards and Technical Regulation Guidelines, which have been published and disseminated to ARSO members, partners and stakeholders in the pharmaceutical industry (ARSO, 2021; Kithome, 2022). Nonetheless, the harmonisation of standards and Technical Regulation Guidelines for products under the broader categories of Medical Devices and Equipment (ARSO TC 78), Pharmaceutical and Medicinal Products (ARSO TC 80), African Traditional Medicines (ARSO TC 82) and Technical Regulation Subcommittee (ARSO CACO WG5) is still ongoing (ibid.). Efficiency and rapidity in harmonising ongoing standards and technical regulations, as well as effectiveness in their adoption, will be crucial to support the expansion and intra-African trade of pharmaceuticals.

3.4.1 Procurement of pharmaceuticals

The main aims of implementing a pooled procurement mechanism include reducing prices through higher buyer bargaining power,

increasing product availability, making procurement more efficient and improving product quality (Parmaksiz et al., 2022). The extent to which these objectives can be realised often depends on the effectiveness of interaction among the key actors – buyers (e.g., hospitals or countries), procurement organisations and suppliers (e.g., manufacturers or wholesalers – in a procurement mechanism. The AfCFTA protocols can influence the effectiveness of these actors.

By increasing the market size through liberalised goods and services trade and an increase in intra-African investment, the AfCFTA can facilitate the entry of more manufacturers of pharmaceutical products, enabling an increase in production, which can lead to per-unit price reductions. The rise in the availability of manufacturers can boost buyers' bargaining power as they have more manufacturers to choose from. Additionally, creating an enormous pharmaceutical market can foster the entry of more buyers. When several buyers come together to buy from a large market, their homogeneity may increase to reflect, for instance, the need for similar specific products to serve similar demographics. A higher level of homogeneity of buyers' characteristics can make aligning the motivations, goals and purpose of pooled procurement easier.

Nonetheless, in Africa, where most inputs or intermediates, chiefly APIs for pharmaceuticals, are primarily imported, the efficacy of a liberalised large market to rapidly grow African manufacturing capacity will depend on access to these inputs. Thus, a reassessment of common external tariffs on imported inputs may be required in the short term to continue to support the growth of African manufacturing.

The level of supply competition can also be determined by the size of procurement avenues, which is influenced by production size. Hence, an increase in pharmaceutical market size and practical implementation of the protocols for fair competition could increase the number of suppliers in Africa. Such an increase could spur competition among suppliers, which is essential for reducing the costs of pharmaceutical products (Wafula et al., 2013, 2014).

3.4.2 Harmonisation regulations

Harmonisation of regulations is the process of making them compatible across countries on the continent so that buyers and suppliers face similar regulations irrespective of the country they operate in. To this end, per the provisions of the protocols, the harmonisation of regulations can affect how buyers and sellers engage in cross-border procurement activity. Also, given the potential relevance of intra-African investment in spurring local manufacturing to support efficient procurement mechanisms, the harmonisation of investment governance per the protocol on investment may be essential.

Adopting standardised and transparent rules and procedures provided by protocols can incentivise suppliers to produce more (Huff-Rousselle and Burnett, 1996). Harmonised rules and regulations make it easier for suppliers to access more consumers in the African market. At the same time, they are required to serve as an incentive to suppliers since they make it easier to produce and supply across borders.

Nonetheless, the fragmentation of legal frameworks across countries means that the enforcement of regulations for medicines has been weak in Africa, contributing to the proliferation of substandard and falsified medicines. This contributes to a preference for imported medicines over domestically produced ones, inhibiting the intra-regional trade of locally manufactured medicines.

On top of the fragmentation of legal frameworks for regulating medicines, many African countries do not have regulatory institutions of the required capacity. A study in 2010 revealed that only 7% of the 46 African countries had moderately developed regulatory capacity, and 63% had minimal capacity (Ndomondo-Sigonda et al., 2021). Poor medicine regulatory capacities are reflected in, among other things, poor inspection practices, ineffective and inefficient licensing and product registration, and poor oversight over clinical trials.

Through the AMRH initiative, policymakers seek to support the strengthening of regulatory capacities and facilitate the harmonisation of regulatory requirements. Specifically, regarding the latter objective, the programme has a Model Law on medical product regulation to attenuate the issue of non-coherent medicine laws across countries.

This could foster faster availability of quality, safe and effective medicines to support pooled procurement, potentially assisting with developing the regional pharmaceutical industry. AMRH is implemented in the context of the AU's Pharmaceutical Manufacturing Plan for Africa to enhance the regulatory environment and support the expansion of the manufacture of medicines. Implementation has already yielded some positive results. A notable example is the improvement in registration timelines, from an average of two to seven years to a median of seven months among EAC countries between 2015 and 2016 (Ndomondo-Sigonda et al., 2021). More harmonisation of medicine regulations will improve the continent's capacity to regulate medical products.

4 Crosscutting issues and synergy assessment

4.1 Poverty impact

Eradicating poverty is impossible without sustainable access to pharmaceutical products. Limited access to medicines is particularly precarious in Africa because the continent has the highest burden of communicable diseases and a significant share of the world's non-communicable disease burden (Narayan, 2016; Bigna and Noubiap, 2019). For instance, because less than 2% of medicines required to treat malaria, tuberculosis and HIV-related illnesses are produced in the continent, these diseases killed approximately 1.6 million people in 2015 alone (Pheage, 2017). The overall adverse effect of limited access to pharmaceutical products is excessive numbers of preventable deaths from preventable diseases and, for children who survive, an impairment in cognitive performance.

Affordability is the cornerstone of access to pharmaceutical products. It can be achieved through several factors, including successfully implementing effective pooled procurement mechanisms. Thus, by creating a large market to support an increase in pharmaceutical manufacturing, successful adoption of the AfCFTA protocols can facilitate the creation of efficient cost-saving pooled mechanisms, contributing to price reductions. The presence of a large pool of manufacturers of pharmaceutical products might not translate into appreciable price reductions if anti-competitive practices are prevalent in the business environment. Hence, stringent anticompetitive provisions, as stipulated in the AfCFTA protocol regarding competition, can bolster competition among suppliers, contributing to price reductions.

Tax and tariff policies also affect access to pharmaceutical products. Taxes and tariffs on imported pharmaceutical products and the inputs (e.g., APIs) used in producing them make them pricier and out of the reach of people experiencing poverty. Currently, the structure of the AfCFTA RoOs stipulates that a pharmaceutical product qualifies for preferential tariff treatment from member countries if it is wholly obtained or has significantly been transformed; inputs sourced from within the continent have to be processed considerably.

Since Africa is mainly import-dependent for APIs and has limited manufacturing capacity for most pharmaceutical products, altering the provisions underlying the RoOs regarding the treatment of

imported pharmaceutical inputs can be crucial for the cost-competitiveness of manufacturers within the continent, which can translate into lower prices for pharmaceutical products. A similar treatment of taxes on traded pharmaceutical products, including imported inputs, can be essential.

An assessment of the state of the African pharmaceutical manufacturing landscape shows a vast disparity in production capacity across countries. Countries like Morocco and South Africa produce about 70–80% of the medicines, while countries in Central Africa import about 90% of theirs (Development Reimagined, 2022). Implementing efficient procurement mechanisms can help make low-cost pharmaceutical products accessible to countries with low production capacity. However, local manufacturing may be viable in some countries, especially for generic medicines. Here, the AfCFTA protocol on investment will be critical to support the flow of African investors to countries with relatively low production capacity.

Aside from access to affordable drugs, the quality of drugs is also essential to their efficacy in achieving health outcomes that improve human capital for a productive life. The potential for AfCFTA provisions to support the harmonisation of regulations and standards can, therefore, support the adoption of high-quality standards for African manufacturers, contributing to higher-quality products.

An expansion of African pharmaceutical manufacturing will increase the number of jobs, helping reduce poverty. Aside from jobs, African governments spend a great deal of money to import pharmaceutical products, which drains foreign exchange reserves and public expenditure. An increase in the industry's localisation can thus reduce these financial strains, freeing up money for more investment in other areas like infrastructure to support poverty reduction.

4.2 Climate and environment

Climate change is already contributing to health issues, and thus increasing the burden on already stretched health systems, especially in developing countries. More specially, climate events such as droughts, heat waves and floods are altering infectious disease patterns, as well as increasing food shortages and air pollution, contributing to rising illnesses. At the same time, health systems contribute 4–5% of national greenhouse gas (GHG) emissions, an amount similar to that of the food industry (Pichler et al., 2019). This implies that the development of the pharmaceutical industry, which contributes enormously to the health sector's GHG emissions, must entail achieving the twin goals of reducing GHG emissions and ensuring sustainable access to high-quality medicines to respond to health issues arising from accumulated climate impacts.

The first implication of the AfCFTA in terms of climate impact is its potential to increase access to affordable pharmaceutical products as

a result of the potential rise in local manufacturing and efficient procurement mechanisms on the continent. Sustainable access to affordable, high-quality, efficacious pharmaceutical products, especially in areas hard-hit by climate change, like North and West Africa, will be crucial in attenuating the health issues induced by accumulated climate impacts.

Second, the AfCFTA protocols on investment governance and IPR could have significant implications for pharmaceutical R&D. This could influence the extent to which the industry can contribute to the impacts of climate change. More pharmaceutical R&D and stringent IPR (to support more FDI inflows) will be required to increase the industry's capacity and produce innovative medicines to respond to health needs. By providing provisions on investment governance and IPR, the AfCFTA can thus help increase investor inflows and R&D in the pharmaceutical sector. As a notable example, most pharmaceutical supply chains in Africa do not have the infrastructure (e.g., cold chains) for adequate storage, delivery and implementation of medicines. Innovations to develop more heat-tolerable medication will be crucial in this regard.

Third, efficient pooled procurement mechanisms, enabled through the potential creation of a sizeable liberalised pharmaceutical market as a result of the AfCFTA, underpinned by harmonised regulations, will influence how much manufacturers emit. Harmonising manufacturing standards will ensure manufacturers across the continent produce more medicines with less environmental impact.

4.3 Gender

Implementing the AfCFTA protocols may have significant implications for gender. These could stem from participation within the pharmaceutical industry and how the protocols affect the accessibility of affordable, high-quality, efficacious pharmaceutical products.

The pharmaceutical workforce will be crucial to the effectiveness of the AfCFTA in improving Africa's health industry. It plays a pivotal role in producing, distributing and implementing pharmaceutical products, which are all salient for developing a robust pharmaceutical industry. Globally, women make up most of the pharmaceutical workforce (Bukhari et al., 2020). Yet they tend to be found primarily in low-paying industry segments, underrepresented in leadership and decision-making roles compared with their male counterparts. One study found that men headed 69% of global health organisations and were board chairs for 80% (Bukhari et al., 2020).

Increasing the representation of women in the industry is imperative not only for gender equality but, more importantly, to drive productive innovation, enhance the standards of medicines, especially those required by women, and ensure more effective decision-making. Specifically, on the innovation-enhancing prospects of gender inclusion, increasing the pool of pharmaceutical workers, especially

in top hierarchies, to include women, ensures that the pool is more diverse regarding knowledge, skills and experiences to support innovative ideas for women-related health needs. Since Africa aspires to leverage opportunities provided through the AfCFTA to develop a robust pharmaceutical industry, this will be an opportunity to make the sector more gender-inclusive to enhance its robustness.

Similarly, in the context of procurement mechanisms, ensuring that women are represented in all categories (buyers, procurement organisations and suppliers) of procurement mechanisms will be imperative for the efficiency and effectiveness of these mechanisms, especially for women-related health needs. More females participating as buyers and in the procurement organisation in a procurement mechanism will increase the potential to use monopsony power (bargaining) and negotiations to procure high-quality medicines more conducive to the health needs of women. Similarly, a more gender-inclusive supplier pool is likely to consider producing medications of high quality that are more conducive to women's health needs.

Job inequality is not the only area in which women are disadvantaged; they are disadvantaged in pay as well. Women earn as much as 29% less than men in the broader health sector (Bukhari et al., 2020). Such disparities can weaken women's contribution to economic prosperity through low labour force participation and less human capital development, among other things.

Aside from these labour market influences, women carry a disproportionate disease burden in developing countries (Iyer, 2020). Considering the case of HIV, women have on average, a 60% higher risk of infection than their male counterparts (Magadi, 2011). Such a broad disparity warrants sufficient women's representation in the whole chain of actors of procurement mechanism agencies to harmonise regulations and standards in the health sector and implement drugs to ensure effective development and delivery of drugs on the ground.

5 Policy recommendations

In the pharmaceutical sector in Africa, two key interests are evident. First, there is a desire to coordinate the procurement of vaccines and other pharmaceutical products at the continental level to leverage cost advantages, such as through the pooled African medicines procurement mechanism of Africa CDC. This collective procurement effort can source products either within Africa or internationally (UCT-ODI, 2024). However, limited production capacity within the continent means procurement is likely to occur predominantly from sources outside Africa. Consequently, RoOs play a significant role in intra-African trade post-procurement. UCT-ODI (2014) contains a wider range of recommendations aimed at developing and strengthening the pharmaceutical industry in Africa, using the AfCFTA as main instrument.

Second, there is a focus on fostering the development of continental value chains within the pharmaceutical sector. Pharmaceutical sectors involve multi-step production processes, including raw material sourcing. These processes have the potential to be localised within regions, offering opportunities to drive Africa's industrial transformation under the AfCFTA.

The AfCFTA can help facilitate these two key objectives.

Implement policy measures to reduce the restrictiveness and associated costs of meeting RoOs for pharmaceutical products while keeping RoOs as is for vaccine-related ingredient inputs and primary and secondary packaging, to promote higher preference utilisation rates and foster the development of global value chains.

The RoOs for pharmaceutical products under the AfCFTA are moderately restrictive. To benefit from the preferential tariff rates provided under the AfCFTA, firms needs to meet these RoOs, which involve compliance costs. Pharmaceutical firms need to decide whether to comply with RoO regulations for preferential tariff treatment or opt to pay the MFN tariff. Given that many African countries already impose zero or near zero tariffs on pharmaceuticals and vaccines, the preferential tariff margins provided by the AfCFTA are minimal. Given these low tariff rates, the pooled procurement initiative may remain largely unaffected by RoOs. Waiving the RoO requirement for pharmaceutical and vaccine products could further simplify procurement.

On the other hand, RoOs also influence firms' decisions on sourcing intermediate inputs and thus the building of pharmaceutical regional value chains and manufacturing. If RoOs are highly restrictive and costly, firms may source within the AfCFTA to qualify for preferential tariffs. Conversely, lenient RoOs may encourage firms to source inputs from outside the AfCFTA, potentially hindering the development of regional value chains. Manufacturing pharmaceutical and vaccine products requires ingredients and primary and secondary packaging. The RoOs for vaccine ingredients and primary and secondary packaging under the AfCFTA are also moderately restrictive. However, unlike for pharmaceutical products, several African countries have higher MFN tariffs for vaccine ingredients and primary and secondary packaging. This means there are significant preferential tariff margins if manufacturers decide to source inputs or produce packaging within Africa. This is particularly significant for pharmaceutical global value chains, where inputs cross borders multiple times. The higher MFN tariffs incentivise pharmaceutical producers to source inputs from within the AfCFTA or encourage non-African firms to relocate to Africa to benefit from preferential tariffs. This could foster local pharmaceutical manufacturing in Africa and the creation of regional value chains. Head et al. (2021) suggest that the relationship between RoOs and regional production resembles a Laffer Curve: RoOs promote regional production up to a point, beyond which firms prefer paying tariffs over compliance.

Therefore, balancing RoOs and tariffs is crucial to support pooled procurement initiatives and the development of local manufacturing in Africa.

Negotiate the relaxation of the current RoOs for pharmaceutical products in pooled procurement scenarios or outline alternative RoOs or procedures for determining eligibility for tariff preferences.

This may permit the importation of products without the need to strictly meet the usual RoO requirements, facilitating trade across borders. Other measures could involve relaxing product-specific RoOs for pharmaceuticals and mitigating compliance costs related to administration and certification. Furthermore, it may be important to consider self-certification of RoOs. Currently, under the AfCFTA, RoO certification must be conducted by an approved exporter or a designated competent authority of the exporting state party. This process can be burdensome and time-consuming, especially for small and medium-sized enterprises. Introducing self-certification, which is currently permitted only for consignments valued below $5,000, could significantly alleviate the costs associated with RoOs for traders. This would facilitate trade within the AfCFTA, promote preference utilisation and support the establishment of regional value chains.

Ensure regulatory harmonisation of medical standards within the pharmaceutical trade sector.

Another significant aspect through which the AfCFTA can contribute to the trade of pharmaceutical products relates to regulatory harmonisation of medical and pharmaceutical standards. At the continental level, efforts are being made to align pharmaceutical and medical regulations and country-specific requirements. This is reflected in the Standards for Pharmaceutical and Medical Devices in Africa Project, created in 2020 through a partnership between Afreximbank, ITFC, BADEA and ARSO. ARSO has already harmonised 113 standards and Technical Regulation Guidelines, which have been published and disseminated to partners and stakeholders in the pharmaceutical industry (ARSO, 2021; Kithome, 2022). However, harmonisation of standards and Technical Regulation Guidelines for products under the broader categories Medical Devices and Equipment (ARSO TC 78), Pharmaceutical and Medicinal Products (ARSO TC 80), African Traditional Medicines (ARSO TC 82) and Technical Regulation Subcommittee (ARSO CACO WG5) is ongoing.

Rapid harmonisation of these products and robust capacity-building efforts to enhance the effectiveness of their implementation will be crucial for enhancing the production and intra-African trade of quality pharmaceutical products.

Reduce tariffs and non-tariff barriers on imported critical pharmaceutical components like APIs to foster the cost-competitiveness of producers of critical final health products.

Although a common external tariff is required to shield African producers to meet the objective of increasing trade and economic integration, this could hamper the growth of the pharmaceutical sector, owing to the paucity in production capacity, especially for APIs. Thus, in the short to medium term, it could be economically beneficial to reduce tariffs and non-tariff barriers on imported critical pharmaceutical components like APIs to foster the cost-competitiveness of producers of critical final health products.

Adopt capacity-building measures to boost the technical capacity of procurement bodies or buyers to improve the efficiency of pooled procurement to serve as a sustainable incentive for the manufacturing of health products.

The technical capacities of buyers or procurers will be crucial to promoting efficient, low-cost procurement of health products. Such capacities, especially in forecasting potential demand and assessing health product needs for a particular demographic group or population, and the ability to assess health product attributes will be vital. To this end, boosting the technical capacity of procurement bodies or buyers will be essential in improving the efficiency of

pooled procurement to serve as a sustainable incentive for the manufacturing of health products.

In the case of regional procurement agencies, financial capacity will be imperative to ensure a predictable budget. This will guarantee the timely procurement of health products, especially for urgently needed health products like vaccines during times of health crisis.

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Appendix 1 HS classifications for selected vaccine-related inputs

Category	Product	Short description	HS code
Ingredients	Thimerosal	Preservatives – to prevent contamination	285210
	Aluminium salts	Adjuvants – to help stimulate a stronger immune response	283322
	Sorbitol	Stabilisers – to keep the vaccine potent during transportation and storage	290544
	Formaldehyde	Inactivating ingredients – to kill viruses or inactivate toxins	291211
	Neomycin	Antibiotics – to prevent contamination by bacteria	2941
	Sterols	Lipid nanoparticles in mRNA vaccines	290613
Primary packaging	Vials	Serum bottles, vials and other pharmaceutical containers of glass	701090
	Stoppers	Articles of vulcanised rubber n.e.s., except hard rubber	401699
Secondary packaging: storage and distribution	Insulated cartons		4819
	Vaccine carriers		901890
	Cold boxes		392310
	Refrigerators/freezer chests		841850
	Freezers		841830
	Dry ice		281121
Secondary packaging: vaccine administration	Syringes		901831
	Needles		901839