Local production of essential health products in east and southern Africa

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Executive summary

Africa continues to rely on imports of Essential Health Products (EHPs) such as medicines, vaccines, therapeutics, diagnostics and health technologies/equipment. An overreliance on imports and an absence of distributed production within the region increases costs and impacts on citizens' access to EHPs. This is especially so in the face of global supply chain challenges, as evidenced during the COVID-19 pandemic. It highlights the need for local production of EHPs as a step towards ensuring improved access to quality health for all.

This paper by Southern and Eastern African trade Information and Negotiations Institute (SEATINI) under the umbrella of the Regional Network on Equity in Health in East and Southern Africa (EQUINET) maps the landscape of local EHP production in four selected east and southern Africa (ESA) countries, namely Kenya, South Africa, Uganda and Zimbabwe, and using the evidence gathered, presents proposals for promoting equitable access to EHPs by promoting capacities for local production of EHPs. In doing so, it builds on more than 15 years of EQUINET programming on local production of EHPs.

An analytical framework was developed. A literature review explored key EHPs and their value chains, identifying measures and indicators for the mapping, together with primary and secondary stakeholders and other evidence sources. These included: analysis of import and export data on key COVID-19 EHPs. *Within countries* it included**:** progress monitoring of existing capacities the production capacity localisation; intellectual property rights (IPR) and local legislation that uses flexibilities to secure access to EHPs; policy space; governance issues; the interests and relationships between domestic private producers and public authorities; and negotiating and purchasing arrangements. *Across countries* it included mechanisms for and incentives and barriers to regional investment; and relevant international and global forums.

The pharmaceutical context: The business environment is critical in promoting or discouraging local production and various measures are being taken to improve it. The East African Community (EAC) is implementing a favourable regime for attracting investment, especially in the manufacturing sector. South Africa has a strong incentives regime to support its local manufacturing industry, although this favours multinational corporations at the expense of small local industry, and is now implementing affirmative action programmes like Black Economic Empowerment (BEE), to support local entrepreneurs. In contrast, while Zimbabwe has a favourable tariff structure, particularly for importing raw materials, its business environment is often handicapped by reactive government policies relating to exchange rates and imports.

Pharmaceutical production across Kenya, Uganda and Zimbabwe is limited and focuses mostly on basic essential formulations, simple analgesics, syrups for children and some creams. This minimal product range suggests limited investment in Research & Development (R&D) to promote innovation and the production of high-tech EHPs for the treatment of common diseases and increasing levels of more complex non-communicable diseases.

Production of essential health products: The findings show that local production of medical devices and personal protective equipment (PPE) is limited to low value products across Zimbabwe, Kenya and Uganda. South Africa produces some diagnostic kits and laboratory reagents. In the other three countries, local production is concentrated on basic PPE, such as masks, gowns and gloves, which do not call for advanced technology.

Health facilities across the four countries were overwhelmed during the pandemic. Demand for oxygen outstripped supply, and with other shortfalls suggested that services were ill prepared to deal with a pandemic of such magnitude. Whilst authorities responded swiftly to increase investment in oxygen plants and concentrators, the speed of the response and the ability to rapidly increase production indicates unfulfilled potential in and inadequate prior political attention on and investment in local production in the region. It did not require a pandemic for Kenya and Zimbabwe to invest in new air separation plants to produce medical oxygen.

Zimbabwe's import and export data show that in 2021, while the country was suffering the effects of various COVID-19 variants, the importation of textile face-masks, without a replaceable filter or mechanical parts, including surgical masks and disposable face masks made of woven textiles decreased by 23%, suggesting that local production of these products increased.

A waiver to the TRIPS agreement, belatedly granted at the June 2022 World Trade Organization (WTO) Ministerial conference, gives temporary reprieve to low and middle income countries lacking manufacturing capacity, but is limited in many ways. Nonetheless, the decision by the governments of Kenya and Zimbabwe to support the proposal on the waiver initiated by South Africa and India is an essential step towards the reform of the IPR regime for technology transfer, innovation and development. Kenya and South Africa are among the six countries earmarked for mRNA technology transfer for vaccine manufacture.

Government initiatives in Zimbabwe to support innovation hubs in institutions of higher learning and in Uganda and Kenya support to industries manufacturing PPE are key steps in the quest to establish local production. The evidence of increased manufacture of PPE, sanitisers and polymerase chain reaction (PCR) tests, plus governments' political support for purchase of locally produced PPE and other related EHPs are positive developments in engendering local production.

The following recommendations are proposed.

In the short to medium term:
The production of active pharmaceutical ingredients (API) is central to improving local pharmaceutical production. ESA countries should engage with multinational corporations holding patents and licenses to build and shape relationships and partnerships to secure API production in a way that ensures such production is profitable, rather than becoming a net drain on the health system.

ESA countries should support their local pharmaceutical sectors through measures such as restricting importation of locally produced medicines and raising import taxes on imported pharmaceutical products that can be manufactured locally;

ESA countries can strengthen measures that exempt duty and value added tax (VAT) on imported raw and packaging pharmaceutical materials to stimulate local production. ESA countries can also provide state incentives to companies that utilise local resources for local medicines production;

On the **TRIPs waiver**, ESA countries should use the provisions of the waiver to pool resources to carry out the associated R&D and establish regional vaccine manufacturing plants, in a regional approach. Larger regional markets are essential for developing and sustaining a manufacturing sector that can produce EHPs to respond to the currently unmet needs of people in the region. Pooling resources and capacities also shares risk and minimises the potential economic impact;

On the obligation to pay royalties when using the waiver, there are provisions in Article 44.2 of the TRIPS agreement which state that member countries may limit the remedies available on payment of remuneration against such use, taking into account the economic value of the authorisation as per Article 31 (h). ESA countries may make use of this option in applying the waiver by using their own laws and legal systems to limit compensation, thus avoiding high royalty payments.

In the longer term:
ESA countries should: ***m***ake resources available for R&D to promote innovation and production of high-tech EHPs; and create a system that links industry and academic institutions to ensure relevant skills development in the pharmaceutical sector within the region.

1. Introduction

Africa's population is estimated at 1.2 billion people, yet the continent is extremely vulnerable to shocks in global supply chains and the trade policies of foreign governments, as evidenced in the lockdowns countries throughout the world imposed on the outbreak of the COVID-19 pandemic in December 2019. By May 2020, about 80 countries had imposed some form of restriction on the export of medical supplies including Essential Health Products (EHPs) medicines, vaccines, therapeutics, diagnostics and health technologies (UNCTAD, 2021).

This paper by Southern and Eastern African trade Information and Negotiations Institute (SEATINI) under the umbrella of the Regional Network on Equity in Health in East and Southern Africa (EQUINET) maps the landscape of local EHP production, with a focus on four selected countries in east and southern Africa (ESA): Kenya, South Africa, Uganda and Zimbabwe.It uses the evidence to identify measures for promoting equitable access to EHPs through increasing local production capacities, building on EQUINET'S more than 15 years of programme work on local production of EHPs.

Definition of EHPs: those health products that satisfy the priority health care needs of the population. They are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms (medicines and vaccines), with assured quality, and at a price the individual and the community can afford (WHO, 2020).

Equitable access to EHPs is important for population health, particularly during a pandemic. In relation to COVID-19, the essential EHPs beyond basic infrastructure like household access to safe water and soap, include alcohol-based hand sanitisers, facemasks and other Personal Protective Equipment (PPE), oxygen, ventilators, therapeutic medicines, vaccines, diagnostics and the related consumables. All of these have been in short supply in ESA countries, particularly at the beginning of the COVID-19 pandemic.

This development renewed calls for Africa and other developing countries to invest in capacity for local pharmaceutical and diagnostics production to ensure access to EHPs and to nurture local solutions to ensure production of and equitable access to EHPs as important inputs for population health, both in times of normalcy and during pandemics.

ESA countries continue to rely on other continents for EHPs. The absence of distributed production in the region and overreliance on that of other continents increases costs and, in the long run, impacts on citizens' access to these and other medical technologies. The COVID-19 pandemic has highlighted the urgent need for local production of EHPs as a step towards ensuring improved access to quality health medicines for all citizens at all times.Access to these health products and services is also dependent on a country having the foreign exchange to secure imports. Financial crises and commodity price volatility can create shortages just as readily as a surge in demand due to a pandemic.

The mainstream development discourse on access to medicines justifies this dependency with the notion that a nation or region should rely on sourcing essential health supplies based on cost (Kaplan and Laing, 2005). This was enabled by globalisation and efficiency rationalisation in orthodox economic theory. It favoured currently large and/or existing producers primarily based in industrialised countries.

1.1. The COVID-19 pandemic

The advent of COVID-19 has seen questioning of the preference in orthodox economics' for cheap price or efficiency, with alarm bells ringing even in the industrialised countries (Correa, 2020). Calls have been made to correct developing countries' dependency on other nations for health products, and for the sharing of production of even the costly-to-manufacture and desirable active pharmaceutical ingredients (APIs), thus reducing dependency on foreign supplies (Correa, 2020; AU CDC, 2020; UNCTAD, 2020; UNECA, 2020).

1.2. Objectives

It is against this background that this paper unpacks the challenge of access to EHPs by investigating the possibility of local production of the various categories of EHP on the continent and mapping a road map to achieve this.

The work seeks to support the ESA region and the African continent achieve equitable access to EHPs to promote health care and wellbeing in line with the norms of human rights, the Sustainable Development Goals and the World Health Organization (WHO)'s Alma Ata Declaration on primary health care. While this is essentially a health issue, it is also an economic, industrialisation and innovation issue for African people.

The paper investigates and presents relevant evidence for policy dialogue to promote equitable access to EHPs by increasing local production capacities through:

a. Mapping the EHP needs of selected ESA countries (Kenya, South Africa, Uganda and Zimbabwe) in relationship to the capacities, measures and resources necessary for local production;
b. Identifying the potentials and gaps to be addressed to implement local production of the various EHPs in the immediate, medium and longer term.
c. Communicating the findings to inform and support national and regional policy dialogue among governments, civil society, policy makers, think tanks, researchers and other relevant stakeholders; and to influence government negotiations on EHPs and the necessary financing streams, as well as sharing on key platforms within the continent, and in critical global platforms that influence the local production of EHPs.

The work focused on both primary and secondary data sources to assess the needs and capabilities and generate the evidence, policy options and choices for African actors engaging in or advocating for self-determination and equity in access of EHPs, as well as for those engaged in negotiations on global financing streams and other platform support to Africa. While the impact of COVID-19 provided the impetus and opportunity for this work, the relevance from its observation and mapping has relevance well beyond the pandemic.

Definitions

1. 'Local' is defined as any production of drugs taking place in low-, lower-middle- and upper-middle income countries, regardless of the ownership structure
2. 'Production' is defined as any stage of the manufacturing process from production of Active Pharmaceutical Ingredients (API), through formulation or packaging.
3. Technology transfer is defined as "a series of processes for sharing ideas, knowledge, technology and skills with another individual or institution (e.g. a company, a university or a governmental body) and of acquisition by the other of such ideas, knowledge, technologies and skills."(WHO, 2011:2)

2. Methods

This paper compiles evidence from secondary data on the current situation in ESA countries towards progress on local production of EHPs. The paper synthesises findings based on country case studies and literature review of published materials relevant to pharmaceutical and EHP production in Kenya, South Africa, Uganda and Zimbabwe. The literature review included published literature (qualitative and quantitative) including studies, policies, legislation, official documents, published materials from the WHO, ESA and Africa regional and other organisations.

An analytical framework was developed from the literature review on key EHPs and their value chains, measures and indicators for the mapping, together with data from primary and secondary stakeholders and evidence sources. The indicators included analysis of import and export data on key COVID-19 EHPs. *Within countries* it included**:** progress monitoring of existing capacities the production capacity localisation; intellectual property rights (IPR) and local legislation that uses flexibilities to secure access to EHPs; policy space; governance issues; the interests and relationships between domestic private producers and public authorities; and negotiating and

purchasing arrangements. *Across countries* it included mechanisms for and incentives and barriers to regional investment; and relevant international and global forums.

2.1. Limitations

The key limitations are shown in *Table 1*, with measures taken to address them. Many relevant publications in this area are not published in public domain. As a result some valuable data may not have been accessed, leaving some gaps in the information required for the study. This limitation was addressed through engaging officials and key stakeholders within governments and during official meetings relevant to the study.

Table 1: Limitations of the methods and their mitigations

Limitation	Measures to address the limitations
Reliability/consistency of evidence across the country	Triangulating different sources of information
Recency of data	
Data gaps in specific countries	
Commercial secrecy	Crosschecking with authorities
Ad hoc nature of some reporting	Crosschecking data against official sources

3. Findings on pharmaceutical production in the region

3.1. ESA's pharmaceutical production context

The Word Health Organization (WHO) recognises that access to essential health products of assured quality for prevention, diagnosis, treatment, palliative care and rehabilitation (WHO, 2022) needs to be addressed. Whilst access to these health products including medicines, vaccines, diagnostics therapeutics and others has been a global concern for decades, this was heightened by shortages and high prices of EHPs essential for management of COVID-19 patients during the pandemic. This put severe pressure on the ability of the region's health systems to provide full and affordable access to quality health care.

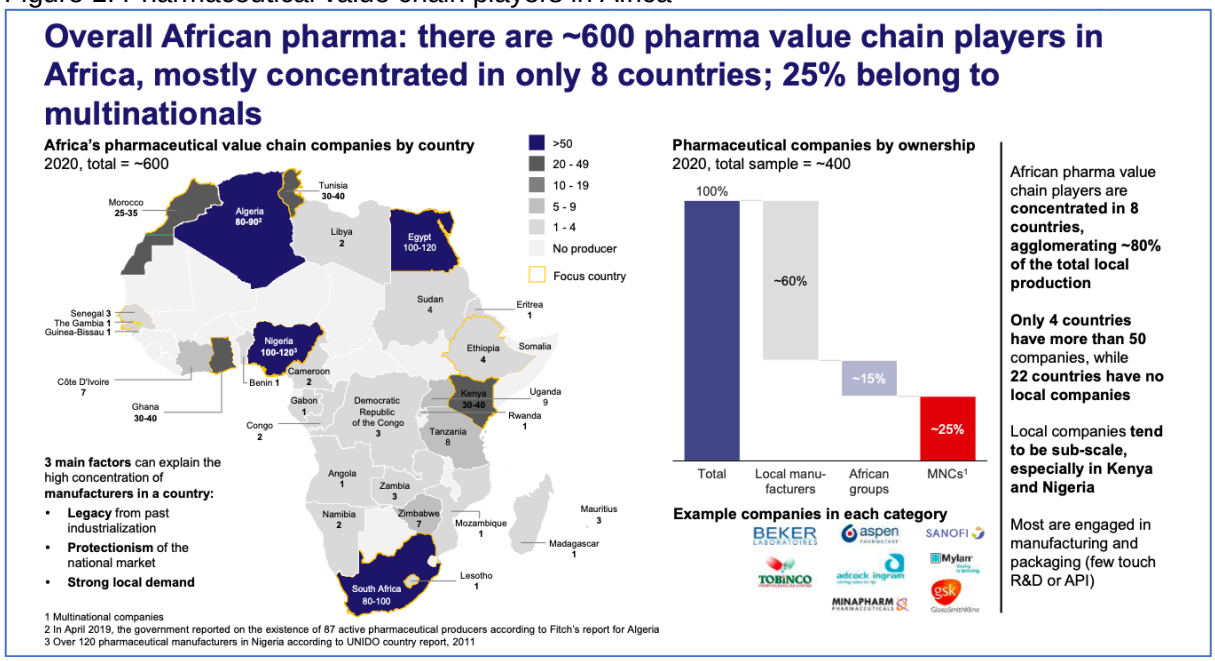
There is no denying that the COVID-19 pandemic has exacerbated long-standing economic and social challenges affecting the region. The pandemic emerged at a time when Africa was finally showing signs of progress on the economic front. According to the UN, at the beginning of 2020, Africa was on track to continue its economic expansion, with growth projected to rise from 2.9% in 2019 to 3.2% in 2020, and 3.5% in 2021 (UNECA, 2020). The advent of the COVID-19 pandemic, spurred ESA governments to innovate and reinvigorate their pharmaceutical industries to increase local production of COVID-19 related health products such as PPEs, sanitiser, oxygen and other medicines.

At the same time, the enablers of growth – technology and innovation – were being increasingly embraced across the continent, with young Africans, who constitute more than 30% of the population, being early adopters of new technological platforms (UNECA, 2020). The inauguration of the African Continental Free Trade Area (AfCFTA) in May 2019, with the potential of boosting local production capacity and intra-African trade was a major milestone towards enabling the transformation of African economies.

Despite the promulgation of industrialisation policies at country and at regional levels, the literature shows that the continent is less industrialised today than four decades ago, when it embraced wholescale liberalisation under the structural adjustment programmes spearheaded by the IMF and the World Bank (Cilliers, 2018). In fact, the contribution of the manufacturing sector to the continent's gross domestic product (GDP) declined from 12% in 1980, to 11% in 2013, and, according to the UN Economic Commission for Africa (UNECA 2020), it has remained stagnant over the past few years,. Manufacturing, including pharmaceutical production, is the cornerstone for industrialisation; a vibrant manufacturing sector boosts productivity across the various sectors of the economy due to its forward and backward linkages (Cilliers, 2018).

In terms of pharmaceutical establishment on the continent, there are about 600 pharmaceutical value chain players, most of which are concentrated in only eight countries, as shown in *Figure 1.* What follows is a discussion of the pharmaceutical manufacturing capacity country by country for the four ESA countries that form part of this study.

Figure 1: Pharmaceutical value chain players in Africa



Source: Fitch, Capita IQ, UNIDO, as cited by Kaufman, Glassman, et al, CGD, 2021

Whilst still in its infancy, **Uganda's** pharmaceutical industry has been on an upward growth trend, and over the last fifteen years, has evolved from two large manufacturing plants registered in the mid-1990s, to fifteen companies of varying sizes today. In early 2010, the country's largest pharmaceutical manufacturer, Quality Chemicals Ltd., received the WHO Good Manufacturing Practices (GMP) certification for production of ARVs and artemesin-based combination therapies (ACTs) for the treatment of HIV/AIDS and malaria, respectively. These firms also manufacture medicines and health supplies including basic essential formulations, tablets and capsules, syrups for children and creams.

Several factors have supported local manufacture of pharmaceuticals and according to a 2010 survey by the United Nations Industrial Development Organization (UNIDO), these include, among others: tax exemptions for imports of raw materials and machinery for pharmaceutical production; improving infrastructure (information technology and water supply); the country's open market economy; and the untapped regional pharmaceutical market (UNIDO, 2010). However, despite the development of the local pharmaceutical industry over the last ten years, Uganda still imports 90% of its EHPs from India and China, according to the Health Sector Strategic and Investment Plan. About 60% of these are distributed by the private sector. Only 7% of local drugs are branded medicines, while the remaining 93–95% percent are generics.

Kenya is the hub of pharmaceutical manufacturing within the East African Community (EAC), with approximately KSH100 billion worth of annual pharmaceutical expenditure, which includes imports to meet local demand. (GoK, 2020). Kenya has an estimated 32 local pharmaceutical manufacturing firms, with the top five pharmaceutical manufacturers exporting 40–85% of their production (Kenya Association of Manufacturers, 2018). Medicine production is concentrated in and dominated by family-run businesses, with the largest 10 firms accounting for almost 80% of local production, and mainly producing unbranded generics in the same market segments (World Bank, 2018). Beyond domestic firms, international pharmaceutical companies are showing increased interest in setting up local manufacturing plants, such as, for example, Square Pharmaceuticals from Bangladesh and Kolon Pharmaceuticals from South Korea (GoK, 2020a).

The Kenyan pharmaceutical industry is primarily involved in the secondary and tertiary levels of production, with only three companies producing raw materials for API production. However, due to underdeveloped local capacity for processing these raw inputs into APIs, these materials are exported.

Table 2: Kenya's pharmaceutical manufacturing industry at a glance

KENYA'S PHARMACEUTICAL MANUFACTURING INDUSTRY AT A GLANCE	
Pharmaceutical market	$1 billion (2018)
Licensed manufacturers	35
Top manufacturers	Beta Healthcare Ltd., Cosmos Limited, Dawa Limited, Elys Chemical Industries Ltd., GSK, Laboratory and Allied Ltd, Regal Pharmaceuticals Ltd., Universal Corporation Ltd.
WHO pre-qualification (PQ) manufacturers	2
Firms in EPZ/SEZ	5
Type of manufacturing	Produce mainly non-sterile products using imported raw materials. Main products: Tablets, capsules, creams, ointments and liquids.
Products	Antibiotics, antiprotozoal agents, analgesics, antihistamines, dermatologicals, antiasthmatics, antimycotics and antacids – 30% of Kenya's demand produced.
Capacity usage	40%–50% (2 shifts)
Export destination	Kenya is the largest producer of medicines in the COMESA region.
	Exports to Tanzania, Uganda, the Democratic Republic of the Congo, Rwanda, Burundi, the Union of the Comoros, Ethiopia, the Republic of Malawi, the Republic of Zambia and the Republic of Mozambique, among other destinations.
Compound annual growth rate (CAGR)	7.6%–12% in next five years
	Kenya is the fastest-growing pharmaceutical market in Africa.
No. of employees	Approximately 4,000; with adequate skills for current product portfolio.
Drug regulatory authority	Pharmacy and Poisons Board of Kenya
Legal requirements for starting a business	Business name or company registration, single business permit Licence to manufacture and sell pharmaceutical products
Legislations that impart pharmaceutical industry	Pharmacy and Poisons Act, Cap 244, Anti-Counterfeit Act, Patent Registration Act, Cap 508, The Factories and Other Places of Work Act, Cap 514, Public Health Act, Cap 242, Food and Drugs and Chemical Substances Act, Cap 254, Environmental Management and Co-ordination Act, and Labour Act, Cap 226.

Source: Vugigi, 2019:17

In **South Africa,** although approximately 276 companies are licensed to import, manufacture, distribute or export pharmaceuticals, there are only 174 manufacturers, 95 of which supply exclusively to the private sector, 15 exclusively to the public sector and 64 to both sectors (Helen Suzman Foundation, 2018). From the sheer numbers of manufacturers, it would seem that the market is highly competitive and conducive to competitive pricing. The pharmaceutical value chain consists of distinct, yet related activities including raw material production, research and development (R&D), manufacture, wholesale, distribution and marketing. Despite the multiple components along the value chain there is very little information in the public domain on the structure of the markets at each stage and the industry appears to be highly fragmented with a diverse range of players active across all levels of the value chain. The manufacturing and retail sectors exhibit high degrees of concentration, while with regard to manufacturing, most companies are active across four therapeutic categories: treatments for HIV, diabetes mellitis, tuberculosis (TB) and cardiac therapy.

The same report notes that the top ten corporations own 58% of South Africa's total pharmaceutical market share . Despite the high concentration of manufacturing, of the 9,244 originator and generic products produced, generics make up 55% of production. In the private sector, five manufacturers have more than 200 registered products: Aspen Pharmacare (607), Adcock Ingram (401), Sandoz (338), Cipla Medpro (223) and Pfizer (219). In the public sector, six manufacturers supply more than 40 products to the public sector: Aspen Pharmacare (106), Fresnius Kabi (63), Cipla Medpro (58); Sanofi Aventis (55), Adcock Ingram (52) and Gulf Drug Company (42). Sonke Pharmaceuticals was established as a Black Economic Empowerment (BEE) venture which together with Aspen Pharmacare. Cipla Medpro and Abbievie supply

antiretrovirals (ARVs), whilst Sanofi-Aventis provides TB, diabetes and epilepsy medicines (Helen Suzman Foundation, 2018). Adcock-Ingram and Sonke focus on generic medicines. Sonke has launched 21 products to date, of which eight are manufactured locally in South Africa (Sonke Pharmaceuticals, 2021). Sonke supplies generic ARVs throughout South Africa and within SADC, to Botswana, Lesotho, Namibia and Eswatini.

According to the Medicines Control Authority of Zimbabwe (MCAZ), **Zimbabwe** has nine registered pharmaceutical companies, four of which are generic manufacturers, whilst the others largely concentrate on trading in only a narrow range of products. CAPS (established in 1952), Datlabs (1950s), Ecomed, ZimPharm and Graniteside Chemicals (1957), Plus Five Pharmaceuticals (Pvt) Ltd (1996), Pharmanova and Varichem Pharmaceuticals (1985) and Zimbabwe Pharmaceuticals make up the list of registered pharmaceutical companies.

Zimbabwe manufacturers produce medicines using mostly imported raw materials and APIs. There are varying levels of installed capacity in developing formulations for both old and new products. Most of the locally produced products are in oral solid and liquid dosages and the country no longer produces parenterals (drips). However, two local facilities for parenteral production of small and large volume are currently being refurbished. One company re-started the production of penicillin in September 2019.

According to the country's pharmaceutical manufacturing strategy (2021–2025), Zimbabwe's pharmaceutical companies are classified as small to medium enterprises (SMEs), indicating that each company has less than US$15 million in annual sales. It states that the industry has a wide product portfolio ranging from 3 to 129 products in various dosage forms and notes that while Varichem previously achieved WHO prequalification to produce an ARV, that status has since lapsed.

The strategy notes that while the country's pharmaceutical market size is small, estimated at US$244.5million with local manufacturers producing US$31.5 million worth of products, the remaining being imports. This suggests a huge deficit in local production. Export of pharmaceutical products constituted about US$3 million in 2019 (GoZ, 2021).

Across the four countries under study common features can be deduced on the pharmaceutical context. The region has a relatively well-established pharmaceutical production footprint that could be leveraged to sustain the long term local production of EHPs. Notwithstanding this, the production lines across Kenya, Uganda and Zimbabwe are limited and concentrated mostly on simple analgesics, basic essential formulations, tablets and capsules, syrups for children and some creams. This limited range of products suggests investment deficiencies in R&D to promote innovation and the production of high tech EHPs for the treatment of both common diseases, and the complex illnesses associated with non-communicable diseases, which are increasing in the region.

Importation of APIs by all the countries also suggests limited investments in technology, skills and research.

Since the region is endowed with vast natural and mineral wealth, one of the most disabling ironies when it comes to manufacturing in Africa is the paradox of the issue of resources. it is a tragedy that the majority of raw materials are imported for the manufacture of only a limited line of products.

3.2. Trade policy and the manufacturing sector

Trade policies are an integral part of a manufacturing system in any given environment. Local production of EHPs, including medicines and vaccines, depends very much on trade policies particularly in the following ways:

- Import duty exemptions on raw materials to include pharmaceutical and R&D inputs.
- Harmonisation of trade and industrial policies targeted at pharmaceutical manufacturers.

- Policy coordination, especially for industrial parks, special economic zones and pharmaceutical parks, etc..
- Ratification and implementation of key trade agreements like the AfCFTA to facilitate intra-regional and continental pharmaceutical distribution (AU Africa CDC PAVM, 2021).

The WTO notes that trade policies influence the business and investment environment. “An appropriate enabling environment should include, *inter alia,* an adequate exchange rate policy whereby investors can retain their foreign exchange proceeds, and the availability of working capital from banks to renew obsolete equipment.” (WTO 2020: 95). For countries intent on boosting local production, particularly in a relatively complex sector like the pharmaceutical and vaccine industries, an enabling environment is key, as these industries are sensitive to factors linked to the productive infrastructure. See *Box 1* on trade policies and the manufacturing sector in Zimbabwe.

Box 1: Trade policies and the manufacturing sector – A Zimbabwe case study

Zimbabwe’s manufacturing is relatively diversified including: beverages; clothing, textiles, leather and its products; pharmaceuticals, chemicals and fertilisers; soaps and detergents; and paper, printing and packaging among others. The sector’s decline as a share of GDP since the last trade policy review in 2011(WTO, 2020) is attributed to absence of an enabling business environment. Reactive policies over recent decades have impacted the sector, leading to foreign currency shortages and industries’ failure to access credit lines from multilateral financial institutions. *Table A* summarises key challenges affecting the sector as noted by the Confederation of Zimbabwe Industries (CZI, 2018), chief among which are “foreign currency shortages causing liquidity constraints; obsolete machinery; the high cost of imported raw materials; and electricity shortages.

Table A: Business environment affecting manufacturing companies, 2018

Measure	Very negative	Negative	No effect	Positive	Very positive
Forex access	81	14	3	0	3
Exchange rate	65	22	8	3	3
Cash shortages	61	31	5	0	3
2% tax on electronic transactions	59	27	10	2	3
Policy instability	54	35	7	4	0
Corruption	52	31	13	3	2
Access to financing	43	28	18	6	6
Ageing equipment	36	42	19	1	2
Competition from imports	35	31	27	3	4
Interest rates	32	43	21	3	2
Power cuts	26	29	31	10	2
Electricity charges	21	31	37	8	3
Environmental requirements	19	23	47	9	3
Conformity assessment	13	28	50	4	6
Domestic demand	12	20	15	39	14
Minimum wage/labour regulations	12	29	46	7	6
Import restrictions	9	4	34	27	27

Source: CZI, 2018 Manufacturing Sector Survey, Table 75.

Fixed exchange rate policies: led to overvaluation of the local currency and arbitrage in the informal market, encouraging industry to rely on artificially cheaper imported raw materials, alongside the unavailability of foreign currency. Industry had to pay upfront for imported supplies, despite being deprived of foreign currency earnings and being made to surrender 40% of export receipts at the prevailing foreign exchange auction rate by the Reserve Bank (RBZ, 2021). Abolition of the US dollar as legal tender in 2019 led to scaling down of production.

The 2015 Consignment-based conformity assessment programme: required imports, including basic raw materials for the pharmaceutical industry (such as ethyl alcohol etc. essential in the manufacture of sanitisers and detergents to prevent COVID-19 spread), to have a certificate of conformity before final customs clearance in the country of origin. Without this, a compulsory assessment process at the importer’s expense was required, including a 15% penalty fee, along with costs for storage, sampling, transportation & testing fees among others.

'Ease of doing business' reforms: The indigenisation law was repealed in 2018 allowing foreign investors to select 100% foreign-owned investment partners (GoZ, 2020). The Zimbabwe Investment & Development Agency Act (ZIDA) Act of 2019, established an investment promotion & facilitation body, repealing and amalgamating other acts and saw the introduction of a more predictable and investor friendly One Stop Investment Services Centre (GoZ, 2020).

Industrial development policies: Prior to 2016, Zimbabwe restricted imports of consumer goods by raising tariffs & extending discretionary import licensing to shield domestic manufacturers from foreign competition In 2017, it issued a consolidated list of products, which the CZI praised, stating that "capacity utilisation increased from 45% to 48% in 2018 while overall output … increased by 12% in the same period (CZI, 2018). In June 2019, the Zimbabwe National Industrial Development Policy (ZNIDP) (2019–23) was adopted to steer industry towards export markets and import substitution. Anchored in innovation, investment & export-led industrialisation, it envisions an increased industrial base to 25% of GDP with development of industrial parks, developed by local authorities in collaboration with higher education institutions & the private sector. Special Economic Zones hosting industrial & other services are also mentioned. A local content strategy also aims to increase local content in priority sectors from 25% to 80% by 2023.

Box 2 summarises some of the policies specifically related to the Zimbabwe's Pharmaceutical Industry as they relate to the provision of EHPs.

Box 2: Zimbabwe's pharmaceutical industry

The Pharmaceutical Manufacturing Strategy (2021–2025) developed in partnership with the United Nations Industrial Development Organization could constitute a model for government support to the manufacturing sector. It's objectives are, by 2025, to:

- Increase market share of local pharmaceutical products from 12% to 35%.
- Increase local production of essential medicines from 30% to 60%.
- Increase sales revenue of local production from US$31.5 million to US$ 150 million.
- Increase new local product registration from 5% to 20%.
- Improve compliance to good manufacturing practice for at least four companies.
- Improve exports of pharmaceutical products from 10% to 25%.

Increased pharmaceutical production measures include increasing local content; commercialisation & patenting of traditional herbal medicines to promote development of new products and farming of traditional medicines to increase medicine output; and utilisation of Science and Technology Institutes to scale up production and investigate new medicinal molecules (GoZ, 2021).

The sector could also benefit from the ***Duty Rebate Facility***, which provides for targeted import duty and VAT exemptions for capital equipment and raw material imports where these are not locally available. The 2019 budget renewed industry-specific rebates for various industries including the pharmaceutical industry. NDS1 notes that there is capacity for the pharmaceutical value chain to increase market share to 60% of essential medicines. Performance is to be improved through the following strategies:

- Promotion of public procurement of locally produced medicines;
- Monitoring sourcing of locally manufactured medicines using the Electronic Logistics Management Information system (e-LMIS);
- Re-capitalisation of the pharmaceutical industry;
- Enhancing the competitiveness of the Pharmaceutical Manufacturing Association and its members;
- Facilitating collaboration between industry, academia and indigenous knowledge systems to formulate new products and establish Bioequivalence centres.
- Export driven growth will leverage the regional pharmaceutical deficit, market proximity and the SADC Free Trade Area.
- Public Health and Industrial Development policies and regulations will be harmonised.

Other innovations will include: A system to monitor expire dates of patent rights; Speedier medicine registration by the Medicines Control Authority of Zimbabwe (MCAZ) and special exemptions for locally produced medicines; Capacity of key public institutions (MCAZ, the schools of Pharmacy and the African Institute of Biomedical Science and Technology will be built; the list of medicines requiring import licenses will be reviewed in line with domestic production capacity (GoZ, 2021).

A comparison of the above policies with those in Kenya, South Africa and Uganda shows many differences, with the policies of these three countries being more favourable to local production.

South Africa, like the other countries, is dependent on multinationals based in the country for the import of pharmaceutical products, particularly APIs, despite of its having some 175 local manufacturers (DTI, 2018). Nonetheless, South Africa has an advantage in terms of local production of pharmaceuticals as compared to other African countries "as it is the only country that meets WHO standards to manufacture pharmaceutical products" (DTI, 2018:148). Still, its dependency on importing APIs places it at greater risk of currency fluctuations. In addition, the trading environment favours the dominant multinationals for pharmaceutical products as these are imported duty free and thus likely to outplay smaller, newly established local producers. The government has, however, reported that it will offer support to small domestic producers.

The country's Industrial Policy Action Plan (2018/19–2020/21) notes specific capabilities developed in the manufacture of certain molecules such as those in ARVs, with six local companies having established competencies in formulating, tableting and packaging ARVs locally. The plan intimates that the government will continue to support the sector providing a significant portion of the state's procurement to local players. In addition, the Government will support industry mechanisms to promote local manufacture against cheaper imports.

Since 2013, for Kenya and Uganda, the WTO reports improvements in the 'Doing Business' environment among EAC countries.

> "Rwanda, Kenya and Uganda have made considerable reforms during the period, Kenya rose in ranking by more than 10 places from 136th position in 2015 to 80th in 2018 and subsequently to 6th. Rwanda moved up 11 places to 29th in 2019 from 41st in 2018. Rwanda is ranked the 2nd easiest to do business in Africa after Mauritius. Uganda's position had improved from 150th in 2015 to 112th in 2018 but dropped to 127th in 2019" (WTO 2019a:8)

Kenya has various duty rebate and suspension schemes available at the regional EAC level; the country offers fiscal incentives in the form of tax holidays, reduced tax rates and investment deduction allowances. These incentives are available under the Export Processing Zones regime and the Special Economic Zone regime (WTO 2019), while sector-specific incentives are available for the manufacturing sector.

3.3. Raw materials and the pharmaceutical industry

The pharmaceutical industry in most ESA countries depends on imported APIs, but the industry's raw materials are impacted by tariffs, which have strangled production processes.

In **South Africa**, all imported pharmaceutical products are tariff-free, which means that raw materials for the pharmaceutical sector pay no duty. However, the bound tariff rate ranges between 10% and 30% for pharmaceutical products, with 15% on medicaments, which are the country's biggest import." (DTI, 2018:148). **In Uganda**, the raw materials for PHPs, especially APIs, are imported mainly from India, China and a number of European countries. According to local pharmaceutical manufacturers the API import process may take up to six months or more, while the prices of raw materials fluctuate frequently depending on market demand. Most packaging materials are available on the local market, except for glass bottles and aluminium. However, several manufacturers prefer to import their primary packaging materials for pharmaceuticals as the locally available materials may not be of the desired quality. A related cost of this problem noted by some manufacturers is that, in order to keep their production lines running, they have to maintain very high raw material inventories, which depletes their working capital.

At regional level, the EAC is implementing a common external tariff (CET), which commenced in 2005, with three bands of: 0% for raw materials and capital goods, 10% for intermediate goods and 25% for final/consumer goods. For products treated sensitively within the community, there are applied tariff rates above 25% (WTO, 2019).

Zimbabwe's imports are governed by the Open General Import License (OGIL), where imports are exempted from licenses, with the exception of some products that require permits from respective government ministries and agencies. The Government says it will implement “a tariff policy aimed at enabling the importation of raw materials and capital goods to stimulate production and export of value-added goods.” (GoZ, 2020). This will be one of the measures utilised to encourage investment in priority sectors, including pharmaceuticals, to strengthen value chains and enhance competitiveness of local industry.

The Zimbabwe Revenue Authority notes that the country's successive tariff rationalisation over the years has produced a cascading tariff structure categorised into raw materials and capital goods with low duties, intermediate goods with moderate duties, and finished goods with relatively high duty rates. The adopted tariff structure takes into consideration the value addition processes obtaining in the economy. The categories and tariff bands are as reflected in **Table 3**.

Table 3: Zimbabwe tariff structure by product category

Raw materials	0–5%
Capital goods	0–5%
Intermediate goods	5–25%
Finished goods	<40%
Sensitive goods	>40%

Source: GoZ, 2020: 21

In summary, the business environment plays a critical role in supporting local production or otherwise. Zimbabwe is handicapped by reactive government policies related to exchange rates despite its favourable tariff structure, particularly for importing raw materials. South Africa has a strong incentives regime to support the local manufacturing industry although this has favoured multinational companies at the expense of small local industries. Hence the country is implementing affirmative action programmes like BEE to raise up local entrepreneurs.

The EAC is also implementing a favourable regime to attract investments, particularly in the manufacturing sector. All these incentives and measures are being implemented to improve the business environment but more support is required, particularly in other non-financial incentives, to support R&D, technology transfer, and linkages between industry and academic institutions for skills development relevant to the pharmaceutical sector and the regional context.

4. Production of essential health products and COVID-19

4.1 Medical devices, diagnostics and PPE

A medical device is any instrument, apparatus, machine, appliance, implant, reagent for in vitro use, software material or related article used for a specific medical purpose (Hubner et al, 2021). Most medical devices have been built for the demands and resources of high-income countries and are not adapted to the challenges of Africa and more-so the challenges of the public health care sector.

The South African private sector is able to absorb and sustain high-end technology and use given the levels of financing, the prescribed minimum benefits governed by the Medical Schemes Act and linked to that – the dominance of third-party voluntary insurance payments for technology for treatment, and most importantly, diagnostic purposes. There is a plethora of devices for diagnostic systems in large-scale laboratories, facility-based testing facilities, point-of-care testing and also self-testing kits for a range of conditions from HIV/AIDS (HIV tests, viral Load, CD4 count), to TB (MDR-TB, XDR-TB), diabetes and, most recently, for COVID-19 related diagnostics at laboratories, drive-in centres, health care facilities and community pharmacies.

However, there are few companies willing to take on the risk of manufacturing given the already low cost; it is simply easier to import test kits for HIV/AIDs and COVID-19. In an interview, it emerged that it was cheaper to import PPE and surgical masks, given the high investment

required just for mask production. This exists in a space dependent on private manufacturing, financing capability and willingness to take on a perceived high risk, with little market certainty.

Importantly, the system of classification by financial risk determines the uptake of local production and market entry. The lower the risk, the greater the likelihood of local production taking place. This is particularly relevant when looking at both medical and non-medical production as came to the fore with the surge in demand for PPE at the height of the COVID-19 pandemic. The PPE debate reaffirmed the national/regional fragility in times of crisis, as well as the importance of the health system.

The issues around PPE and medical devices have shown serious challenges caused by dependency on imports and the flooding of markets by poor quality imported PPE. In a discussion with a private investment firm looking at entering the PPE manufacturing space, the key issue was the competitive pricing of PPE from China indicating the extent to which local manufacturing and production is neither geared towards flexible specialisation and adaptation, nor viable relative to global competition.

In **Kenya***,* the Government relies on already existing production facilities to fulfil public needs in PPE for distribution at both national and county level health facilities and public health workers, which was procured through the Kenya Medical Supplies Authority. Kitui County specifically, shifted production at county-owned textile factory, Kitui County Textile Center (KICOTEC), from garments to face masks (surgical and woven).

The Kenya Bureau of Standards (KEBS) has developed standards for PPE manufacture including: hand sanitisers; surgical masks; gloves (surgical and medical examination); face masks for public use; face shields; and protective clothing, that are freely available to manufacturers. In addition, the Kenya Association of Manufacturers (KAM) partnered with the Kenya COVID-19 Fund Board and Equity Group Foundation to build the capacity of local manufacturers to increase production and enhance the quality of PPE. The UK Department for International Development (DFID) and Ministry of Trade, Industry and Enterprise Development have also partnered to train local manufacturers in improving PPE quality to meet KEBS and British and European Standards.

In Uganda, a number of SMEs are producing PPE for consumption by both the local public health and private sectors. Some have adopted 3D-printing technology normally used to produce orthotics for physical rehabilitation to create protective face shields for health professionals on the frontline of the pandemic. One SME in the Gulu district in the northern part of the country, is combining many approaches to produce PPE and protect the environment through plastic waste management (see *Box 3*)

Box 3: Ugandans male plastic waste into coronavirus face shields

Prior to the COVID-19 pandemic, Takataka Plastics made roofing tiles and pavers from collected plastic waste, until the Ugandan government shut down workplaces to contain the pandemic. The business quickly developed prototype plastic face shields and posted pictures on social media. The hospital had just received its first COVID-19 patient and immediately requested ten face shield masks. Making the face shields is a two-day process; the plastic is sorted, cleaned, shredded, melted and moulded and an adjustable strap is attached. They make single-use shields (costing about one US dollar) and reusable ones (costing about US $2.70). Between March and June, Takataka Plastics manufactured some 1,200 face shields, selling 500 to NGOs and private health facilities and donating 700 to public hospitals.

COVID-19 severely disrupted global supplies of personal protective equipment (PPE), that badly affected poorer countries; medical workers threatened work boycotts due to the lack of PPE and the Uganda Ministry of Health warned that they would likely run out of PPE within three months. Uganda throws away some 600 tonnes of waste plastic daily but less than 5% is recycled. Even in Gulu, where Takataka operates, only 20% of plastic waste is collected, ending up in waterways and on vacant land and Takataka plans to expand into a full-scale plastic processing plant recycling nine tonnes of plastic waste monthly, up from the current 60kg a day.

Source: Okot, 2020

In summary, local production of medical devices and PPE is limited to low value products across the three ESA countries, with the exception of South Africa, which produces some diagnostic kits and laboratory reagents. In Kenya, Uganda and Zimbabwe, local production concentrates on PPE such as masks, gowns, gloves etc., which do not require high tech skills. These countries need improve technological investment and start producing the high tech medical devices that are critical in the prevention and treatment of disease.

4.2. Therapeutics: access to medical oxygen a constant challenge

The WHO observed that throughout the COVID-19 pandemic, affordable and sustainable access to medical oxygen was an ever-present challenge in most countries, but particularly in low- and middle-income countries. Oxygen is an essential medicine, and despite being vital for the effective treatment of hospitalised COVID-19 patients, access in many low-income countries its availability was constrained due to cost, infrastructure and logistical barriers.

Against the backdrop of widespread oxygen shortages around the world, the ACT-A Oxygen Emergency Taskforce was launched on 25 February 2021 at the WHO. It brought together UN, donor and NGO partners to: assess oxygen needs in low- and middle-income countries; to support oxygen-related funding requests to the ACT- Accelerator; procure oxygen products; and increase access to oxygen in low- and middle-income countries. Taskforce members mobilised around US$700 million in grant financing to help low- and middle-income countries avert oxygen shortages and ensure that it was front and centre of the COVID-19 response. This was an opportunity for countries with no manufacturing capacity to tap into the resources availed for procuring oxygen-related therapeutics.

In South Africa and the other ESA countries, oxygen concentrators have been a much sought-after medical device which has been added to the South African Health Products Regulatory Authority (SAHPRA) dossiers for approval. However, due to stretched regulatory capacity and oversight, large numbers of imported devices purchased for around US$600 made it onto the market, mostly for home use. There was also a shortage of ventilators in hospitals and make-shift COVID-19 sites – part of the global shortage and surge in demand globally. Some of the imported oxygen concentrators had no emergency power supply (EPS), resulting in reported deaths as a result of machines failing during power-outages. This demonstrates the pressing need for enhanced regulatory capacity to fast-track approvals and licensing to protect the public.

In Kenya, the country's only oxygen production firm, Hewatele, had to invest to double its production in response to surging demand from hospitals treating critically ill COVID-19 patients. The country's health ministry reported that demand more than doubled to 880 tonnes from 410 tonnes before the pandemic, leading to shortages due to lack of installed capacity. Consequently, Hewatele, announced that it was building an air separation unit to produce liquid oxygen in 2021, which resulted in a ten-fold output increase to 20 tonnes per day (Reuters, 2020).

In the middle of the pandemic, in August 2021, **Zimbabwe** commissioned its first medical oxygen manufacturing plant by state owned entity, Verify Engineering, to boost its fight against COVID-19. The oxygen plant operates under the Harare Institute of Technology, an institution of higher learning that has joined the local production line. At the time of the launch, the Verify Gases oxygen plant was producing five tonnes of liquid oxygen and 10 tonnes of gaseous oxygen per day in each of two units. The company aims to provide local oxygen production over the whole country in time (New Ziana, 19 August, 2020)

According to the WHO, oxygen therapy remains the first line of treatment for those with severe and critical COVID-19 infection in low-resource settings. The commissioning of the Zimbabwe plant increases access to medical oxygen in hospitals, ensuring safe oxygen therapy for patients. The WHO believes that investments in oxygen plants will reduce COVID-19-related deaths and

strengthen health systems for the long term, helping them to make progress on many of their Sustainable Development Goal targets, including reducing deaths among new-borns, children, women in childbirth and adults with both communicable and non-communicable diseases (WHO, 2022).

Cognizant that access to oxygen can make the difference between life and death for patients with severe COVID-19, the **Uganda Government,** working with partners, ramped up the installation of oxygen plants in major hospitals that manage COVID-19 cases. High tech, high volume, high flow and high purity oxygen plants were procured and installed at the Mulago National, Entebbe, Mbarara and Kayunga hospitals, as well as other regional referral hospitals. Regular supply of oxygen cylinders was made available to other COVID-19 treatment facilities, while later in the pandemic, the private sector was allowed to manage COVID-19 cases and they too developed capacity to provide oxygen to patients.

To conclude, experiences across the four countries show that the demand for oxygen far outstripped supply during the pandemic, suggesting that countries were ill prepared to deal with a pandemic of such magnitude. Whilst the pandemic stimulated the authorities to invest in oxygen plants and concentrators, the swiftness of the response and the ability of the countries to increase production indicates the potential for local production, where there is political and economic will. For example, It did not require a pandemic for Kenya and Zimbabwe to invest in new air separation plants for the production of medical oxygen.

4.3. Vaccine production in ESA countries

The WHO has observed that levels of population immunity vary based on access to vaccines, vaccine uptake and hesitancy, and waning protection from vaccines and prior infections over time (WHO, 2022).

Whilst **Zimbabwe** seems to be committed in other areas of boosting local production of EHPs, particularly PPE and other pharmaceuticals, there is no evidence suggesting progress in establishing vaccine production facilities.

The **Kenya** pharmaceuticals investment profile notes that “vaccine production provides a investment opportunity given that, presently, all vaccines in Kenya are imported. Furthermore, Kenya’s industrialisation agenda and the pharmaceutical policy promote local production. Discussions are underway between a Kenyan firm and Merck for a joint venture in vaccine production,” (Vugigi S, 2020:27)

South Africa, has an Expanded Programme of Immunisation (EPI) and vaccines account for 15.6% of public sector procurement ,yet there has been little movement towards developing and strengthening local production of vaccines. BIOVAC, a public-private partnership established to import, export, package, test and distribute vaccines, is a major initiative aimed at lowering the cost of vaccines, yet it will only commence manufacturing of the Pfizer vaccine for export to the AU by the end of 2021 and early 2022. It was only in 2021 that a South African company, Aspen, received an international license to manufacture the single-dose Johnson and Johnson COVID-19 vaccine. In essence, the local company has been contracted by the global multinational corporations – Janssen Pharmaceuticals Inc and Janssen Pharmaceuticals – to manufacture the vaccines. Capacity exists to ‘locally’ produce a COVID-1 vaccine with a global corporation within South Africa, but this has not been rigorously and robustly negotiated or interrogated in terms of development and manufacturing cost.

The key lesson from the COVID-19 pandemic is that local production of pharmaceuticals to cater for the needs of the health system in a crisis or emergency is virtually non-existent, and unplanned for. The level of global dependence is still high, despite the presence of CIPLA Medpro, an Indian multinational corporation with a large market share in India and globally and ready to make inroads in the global pharmaceutical arena. South Africa and the region can learn valuable lessons from such companies that offer a potential platform and foundation to stimulate

local production to meet the health system's goals of equity, access and affordability, whilst also contributing to manufacturing output and economic growth.

A comparison of the four countries under study shows that the vaccines (all imported) secured so far (as at 1 May 2022), are insufficient to cover the entire population. Only Zimbabwe and Uganda had received vaccines that could cover more than 60% of the population, considered enough to achieve herd immunity. Kenya and South Africa had received vaccines to cover fewer than 40% of their populations.

Figure 2: South Africa vaccines supplied and administered (as at May 2022)

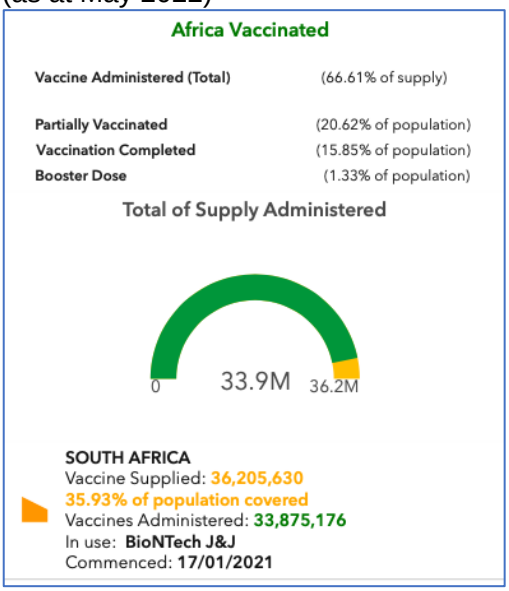


Figure 3: Uganda Vaccines supplied and administered (as at May 2022)

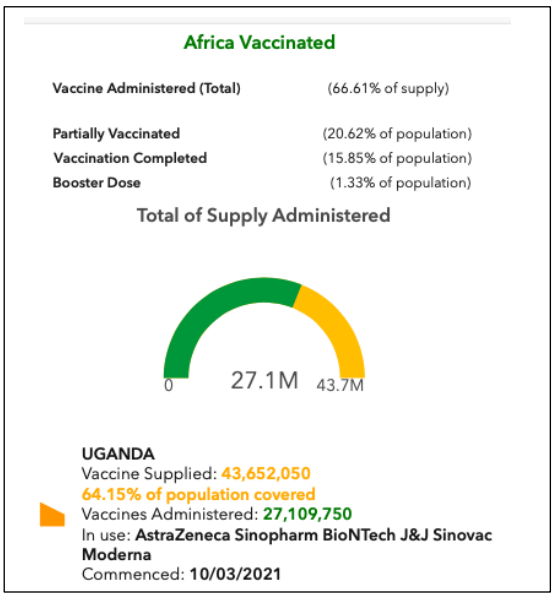


Figure 4: Kenya vaccines supplied and administered (as at May 2022)

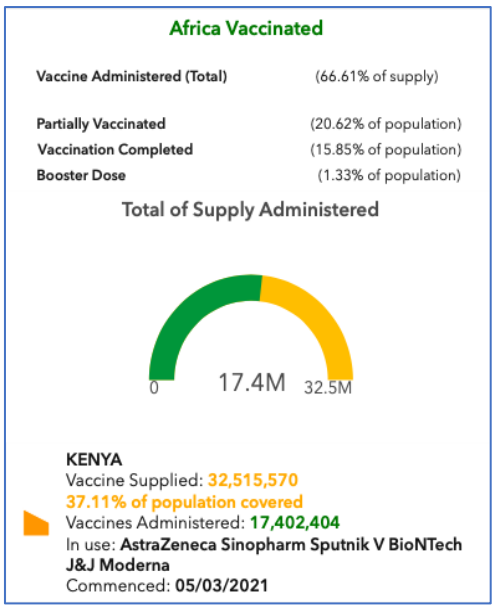
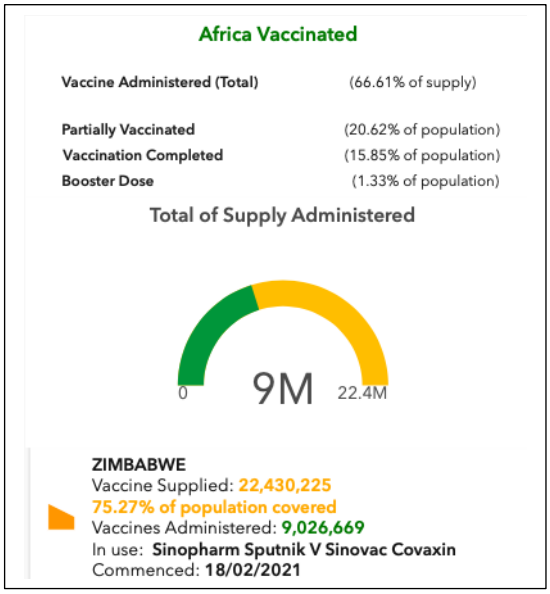


Figure 5: Zimbabwe vaccines supplied and administered (as at May 2022)



Source: Africa CDC vaccine board, 2022

Whilst Uganda and Zimbabwe are not among the vaccine manufacturing hubs earmarked for mRNA technology development on the continent, their installed capacity of pharmaceutical production and history of successful immunisation of their populations provide an advantage, should vaccine production start on the continent.

According to the WHO, the global mRNA technology transfer hub was established in 2021 to support manufacturers in low- and middle-income countries to produce their own vaccines, ensuring that they have the necessary operating procedures and know-how to manufacture mRNA vaccines at scale and according to international standards.

While the hub was set up to address the COVID-19 emergency, it has the potential to expand manufacturing capacity for other products as well, putting countries in the driver's seat when it comes to the vaccines and other products needed to address their health priorities. As the WHO further notes, "Depending on the infrastructure, workforce and clinical research and regulatory capacity in place, WHO and partners will work with the beneficiary countries to develop a roadmap and put in place the necessary training and support so that they can start producing vaccines as soon as possible" (WHO, 2022a).

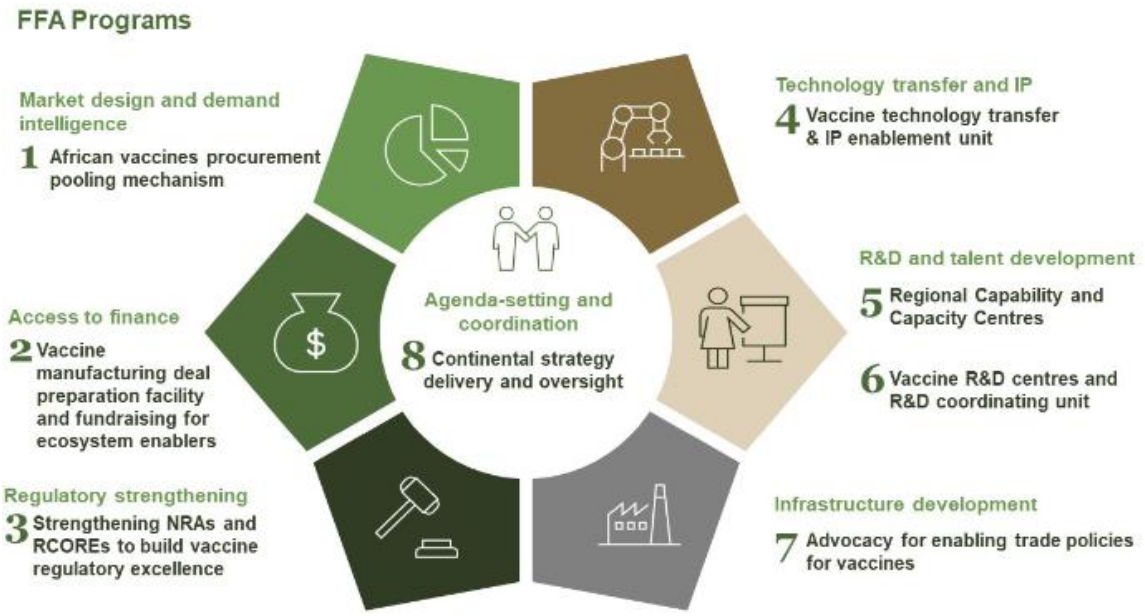
The Partnerships for African Vaccine Manufacturing (PAVM), was established by the African Union (AU) in 2021 to deliver a bold goal: to enable the African vaccine manufacturing industry to develop, produce, and supply over 60% of the continent's total vaccine doses by 2040, up from less than 1% today (with interim goals of 10% by 2025 and 30% by 2030). This could make the difference to African health care, lacking since the countries gained their independence from colonial rule (AU, Africa CDC, 2022).

In April 2021, African leaders gathered to develop a roadmap to achieve vaccine production on the continent. The leaders agreed on a continental strategy – a Framework for Action adapted to regional specifics (AU, Africa CDC, 2022). Consequently, the Africa CDC was tasked with the responsibility to coordinate the various stakeholders across the continent to lay out the key interventions needed to enable the development of a sustainable vaccine manufacturing industry in Africa. To this end, PAVM has identified eight broad programmes (see *Figure 6* below), to support vaccine manufacturing in Africa. Manufacturing is currently taking place in only five countries – South Africa, Morocco, Tunisia, Egypt, and Senegal – that are supplying less than 1% of global vaccine supply. If implemented to their logical conclusion, PAVM's bold programmes will see Africa become more self-reliant in addressing its vaccine needs.

These programmes advocate for implementation of an African vaccines procurement pooling mechanism to provide certainty for African manufacturers:

- strengthening National Regulatory Authorities and Regional Centres of Regulatory Excellence to build vaccine regulatory excellence;
- establishing a Vaccine Manufacturing Deal Preparation Facility to help manufacturers build compelling business plans for investors and to support project financing for vaccine ecosystem enablers;
- establishing a Vaccine Technology Transfer & IP Brokering Service to link technology providers and recipients to an ecosystem of support for tech transfers;
- forming vaccine research and development centres and an R&D coordinating unit to manage research conducted on the continent;
- establishing Regional Capability and Capacity Centres to enhance human capital; and
- supporting enabling trade policies for vaccines – all guided by a continental strategy with a delivery and oversight mechanism (AU, Africa CDC, 2022)

Figure 6: Framework for action programmes for vaccine manufacturing in Africa



Source: AU, Africa CDC, 2022:12

4.4. COVID-19 related EHP imports

Zimbabwe experienced a surge in COVID-19 cases in the period 2020–2021 that also saw an increase in the importation of products meant to help fight the spread of the disease. The imports of COVID-19 materials for the year 2020 and 2021 generally show some increase, particularly in those products for which the country had no manufacturing capacity. For example, the import and export data shows that the importation of “textile face-masks, without a replaceable filter or mechanical parts, including surgical masks and disposable face masks made of woven textiles” decreased in 2021 by 23%, when the country was suffering from the effects of different variants of the COVID-19 virus (delta, omicron etc). This decrease in importation while experiencing widespread usage also suggests an increase in the local production of these products.

The data also shows a massive increase of 833% in the importation of COVID-19 test kits (immunological products put up in measured doses or packaged for retail sale) with a value of USD4 060 000 in 2021, compared to USD435 000 in 2020. Similarly, there was a 57% increase in the importation of COVID-19 test kits (prepared and packaged diagnostic or laboratory reagents). These are high value technology-based products that were not produced locally, putting a higher burden on scarce foreign currency (TrendEconomy, 2022).

Notwithstanding this challenge, in 2021 the country’s national newspaper, the Herald, reported that the National University of Science and Technology (NUST) (one of the innovation hubs announced by the Government) would start producing polymerase chain reaction (PCR) kits in February 2022 following delivery of a US$86 000 reagents manufacturing machine (The Herald, 25 January 2022).

Since the outbreak of the COVID-19 pandemic, “the country has been importing PCR kits for Covid-19 tests but last year, government released funds to NUST to procure the Oligomaker reagents manufacturing machine (DNA Synthesiser), which should reduce test costs by at least 60 percent.” As the newspaper noted, at the start of the pandemic, PCR test costs were around US$60, which was reduced to USD20–30, as more laboratories started testing. With NUST commissioning the machine, costs will reduce further. Besides making Covid-19 testing kits, the machine can also make reagents to test for other viruses including HIV.

The Herald further reported that NUST's financial capacitation was part of the Government's efforts to ensure local higher and tertiary institutions become active players in solving national challenges through innovation at the institutions' innovation hubs, including in boosting local production of EHPs. The Denmark-based manufacturer of the Oligomaker machine was earmarked to provide training to NUST staff on its usage. This machine would be the first DNA synthesiser in the country and will help service other universities, research centres and laboratories that use PCR sequencing to detect diseases *(*The Herald, 25 January 2022).

In Kenya, the Kenya Medical Research Institution (KEMRI) has developed point-of-care testing (PoCT) kits and are currently in production. Once the kits are in place, they shall undergo prequalification by the WHO and Africa Centres for Disease Control and Prevention (Africa CDC). KEMRI also has plans to develop PCR kits. It is reported that COVID-19 primers have already been availed by collaborators and they are in the process of procuring the DNA synthesiser (KEMRI, 2021).

4.5. The WTO TRIPs waiver and local production

Customs duties on imports of essential medical products and equipment impact the movement and accessibility of such products and contribute to the higher costs of these essential products at a time of global health crisis. Nonetheless, these tariffs may also be an essential source of government revenue, with Zimbabwe, for example, charging more than 30% 'most favoured nation' duties on PPE prior to the pandemic. But in 2020, many countries in the ESA region waived import duties on COVID-19 materials and the temporary suspension of customs tariffs on essential medical products and equipment saw an increase in the importation of products such as COVID test kits (Chidede, 2020).

Technology transfer in the manufacture of EHPs remains a critical enabler of local production. ESA countries, together with others beyond the region have intensified global demand to address key constraints in access to key health technologies. In October 2020, India and South Africa with Eswatini, Kenya, Mozambique and Zimbabwe as co-proposers, along with countries from other regions, requested that the General Council of the WTO waive the implementation, application and enforcement of four forms of IPRs covered by the TRIPS Agreement for a specified period, to enable the prevention, containment and treatment of COVID-19.

The scope of the proposed waiver covered copyright and related rights, industrial designs, patents and trade secrets and was initially met with resistance during TRIPS council discussions at the WTO., "… at the WTO's TRIPS Council meeting on 16 October, the United States, the European Union, Japan, Norway and Brazil, among others, repeatedly raised questions and the US constantly emphasised the importance of innovation during the COVID-19 pandemic for safe and affordable medical solutions, without considering the issues raised by South Africa and India" (TWN, 2020). The EU was adamant that it did not see intellectual property as a barrier, maintaining that other factors, such as health infrastructure and lack of materials were more relevant. The US eventually changed course and announced its decision to support the waiver, signalling its willingness to participate in the text-based negotiations as demanded by the waiver's sponsors. This left the EU, UK, Switzerland and other countries still opposed until the Ministerial conference was held in June 2022 in Geneva.

The 12th WTO Ministerial Conference was held from 12–7 June 2022 and concluded with the adoption of the so called 'Geneva package' that included the waiver of certain requirements concerning the use of compulsory licences to produce COVID-19 vaccines under the TRIPS Agreement. The waiver grants eligible members the legal rights to 'limit' the application of provisions of Article 28.1 of the TRIPs agreement "by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic" (WTO, 2022, See *Box 4*). The subject matter referred to includes the ingredients and processes necessary for the manufacture of the COVID-19 vaccine.

Box 4: What does the waiver adopted in June 2022 cover?
The waiver exempts WTO Member States from being sued under the WTO dispute settlement body should they choose to waive certain IP obligations in a pandemic. It also grants the legal right to not grant or enforce patents and health-related IP products and technologies relating to COVID-19, creating the policy space for countries to increase collaboration on COVID-19 vaccines, etc.. It also guides national IP offices, policy makers and courts in de-prioritising IP protection and enforcement, reducing litigation risks for producers and suppliers, allowing them greater freedom to operate. The waiver also lessens some of the more serious restrictions of WTO rules to overcome IP product barriers (MSF, 2021)

In clarifying the use of the waiver, the WTO noted that an eligible Member may authorise the use of a patent's subject matter without the right holder's consent, through any instrument available in the law of the Member, such as executive orders, emergency decrees, government use authorisations, and judicial or administrative orders. This means that eligible members can utilise any of the instruments noted above as provided for in their constitutions.

5. Discussion

There is no doubt that the COVID-19 pandemic has invoked new thinking and reignited old debates on long term polices to build strong systems capable of responding to the needs of the people. Across the four countries several domestic, indigenous companies have found a niche in the production of hand sanitisers, gloves, masks, liquid soap and other essential health technologies such as ventilators, to help respond to the challenges of COVID-19. Universities, technical colleges and government agencies have chipped in to support processes including the manufacture of simple thermometers. If supported, these small but essential steps could revolutionise the production structures of African economies and generate a period of re-industrialisation.

The findings on the pharmaceutical context of the ESA region in *Section 3* confirm the challenges faced by the manufacturing sector as it is influenced by a number of factors. Despite efforts to increase the region's pharmaceutical manufacturing base, this will continue to be impacted by inadequate infrastructure, rising energy costs, shortage of human resources and exchange rate and trade policies, among others. However, countries that have improved the business environment did not automatically translate these 'achievements' into the establishment of local production. Other policies, particularly on those industrial development policies linked to tax and incentives, play a crucial role.

The concentration of countries on producing of a small range of products suggests deficiencies in investments in R&D to promote both innovation and the production of high tech EHPs for the treatment of both common diseases and the complex illnesses associated with non-communicable diseases.

The importation of APIs by all countries also suggest limited investment in technology, skills and research.

5.1. Progress in local production of EHPs

As noted in *Section 4,* the progress in local production of EHPs is limited to low value products across three of the four ESA study countries, with the exception of South Africa, which produces some diagnostic kits and laboratory reagents. This observation confirms the importance of technology transfer to enable innovation and diversification of production.

***In Kenya**,* the fact that the Kenya Bureau of Standards (KEBS) has developed standards for the manufacture of PPEs as reported in *Section 3,* indicates a commitment towards the long term establishment of local production anchored on sound policies, regulations and international standards. The training of manufacturers to meet standards that go beyond Kenya suggests that the country envisages exporting these products by taking advantage of its relatively established textile industry.

***In Zimbabwe**,* import and export data shown in *Section 4.4,* shows a massive decrease in the importation of protective garments made of textiles, rubberised or woven fabrics, and plastic face shields, as well as protective garments made from plastic sheeting. These materials are key components in the manufacture of masks that were key in reducing the spread of COVID 19. This decrease in imports of such key components whilst the country witnessed an increase in the production of masks using such materials, suggests the use of local materials in the manufacture of such products. A number of local SMEs and individuals produced cloth masks in large quantities, while schools and companies (both private and public) as well as government ministries, departments and agencies contracted local producers to manufacture branded masks, customised to the customer's specifications and in different colours, using screen-printing, embroidery or vinyl printing. The government of Zimbabwe made a deliberate effort to buy only locally manufactured PPE for the health sector to boost local production capacity.

Cloth face masks are affordable, washable, less expensive, and generally accessible to the public and were accepted as a cost-effective measure for protecting people and reducing the spread of the virus. Some businesses took advantage of the masks to advertise their business by branding them with company logos, messages or products.

Section 4 on the findings on import of COVID-19 related materials for the years 2020 and 2021 demonstrates how local production saved both foreign currency and lives, as EHPs were produced quickly and made readily available to people.

5.2. Trade policies and the pharmaceutical industry

Section 3.2 noted the impact of trade policies on the manufacturing sector, including the pharmaceutical sector. The case study on how policies affect manufacturing in Zimbabwe reveals the impact of different policies, including the application of tariffs.

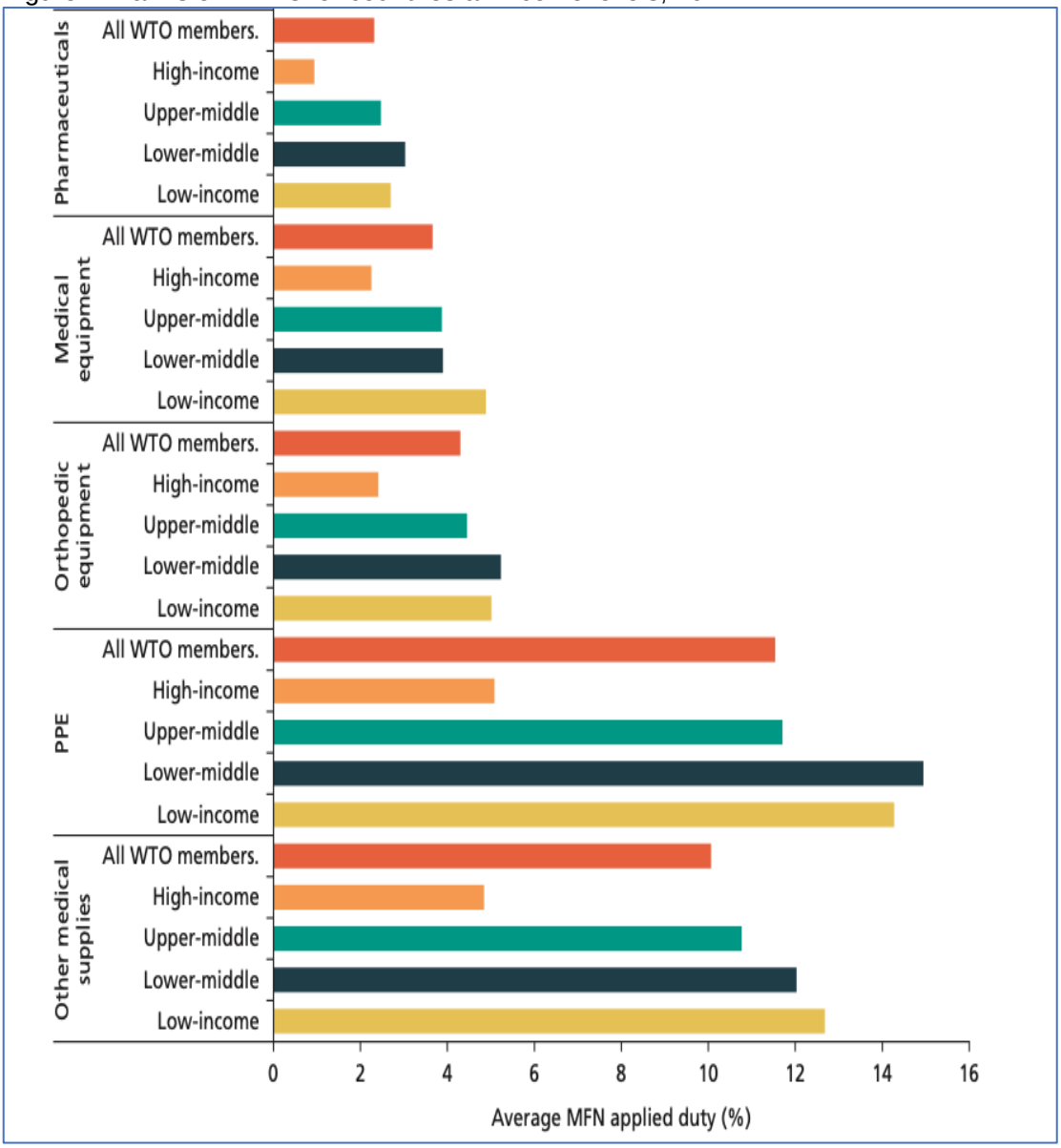
Most countries in the ESA region have a wide range of policies that may affect manufacturing and trade in EHPs. For example, the WTO and World Bank tracked the impact of policies such as "tariffs, prohibitions, and import and export licenses" and others, which have indirect impact, such as "trade facilitation measures; services trade policies (for example, transport, logistics, insurance); regulatory frameworks; and intellectual property rights, which can foster innovation and access to health technologies—along with facilitation of technology partnerships, transfer of technology through production chains, and knowledge spill overs." (World Bank and WTO 2022:59).

As was noted in Section 3, in some countries, tariffs may help boost revenues and support domestic industry, whilst elsewhere, low tariffs may benefit consumers by lowering the prices of goods. *Figure 7* overleaf illustrates the impact of tariffs across various EHPs.

Low to zero tariffs, particularly on raw materials, may stimulate domestic industry to import APIs for local production of EHPs. As shown in **Section 3,** all the countries under study have low tariffs on raw materials, making the increase in local production possible. However, the challenge may lie in the fact that the raw materials must be purchased in foreign currency, making them expensive depending on exchange rate movements. However, the same may not be the case with finished products, where it becomes cheaper to import, thereby discouraging local production, as was the case with COVID-19 test kits in South Africa, discussed in **Section 4.1.**

As seen in the case of Zimbabwe, while the tariff policy favours local production, this must be coordinated with and supported by other policies that provide an enabling environment for manufacturing. The government policy to purchase only locally manufactured PPE encourages local production and should be extended also to other EHPs like essential medicines. However, other policies, such as the exchange rate policy and the Consignment-Based Conformity Assessment Programme militate against the favourable tariff regimes and purchasing policy. Policy coordination is essential if increased local production and import substitution is to be realised.

Figure 7: Tariffs on EHPs for countries all income levels, 2022



Source: World Bank, WTO, 2022

In 2020, the country's vice president, who is also the Minister of Health and Child Care was quoted by the media saying, "Going forward, we need to develop our capacities and never beg again in future but to do things ourselves. Let us develop that capability to develop and build our country. Technology is not a preserve for anyone. If we do not have that technology, we acquire it" (in Chingwere, 2021)

In the context of COVID-19, and at the beginning of the outbreak, the ESA region was heavily exposed because of shortages and, in some cases, non-existent EHPs such as PPE, ventilators, diagnostic kits, therapeutics, medicines etc. In response, the countries studied implemented temporary export measures banning the export of such EHPs and promulgated statutory instruments to support this. Other ESA countries did the same, such as the measures implemented in Botswana, Kenya and a host of other southern African countries.

These actions to a large extent confirmed or exposed the dangers and ruthlessness of the neoliberal policies that have led to these countries being disarmed in terms of their capacity to produce essential products like EHPs. Structural Adjustment Programmes (SAP) had the effect of decimating the industrial capacities of many countries and resulted in de-industrialisation. In

banning the exports, government authorities were reemphasising some critical issues, especially the need for regulation, for supporting local industries to meet the needs of the people first and for national self-determination.

These issues relating to policy space were all eroded during the SAP era and subsequently, the era of the WTO and trade liberalisation. Countries no longer owned the policy space to implement the measures necessary to stimulate economic growth without attracting negative attention from the industrialised WTO members. The COVID-19 pandemic provides an opportunity to revisit some of these policies in order to right the wrongs of past, ill-informed and rushed trade liberalisation policies, as the only way for countries to extricate themselves from being mere recipients of aid and providing markets for goods supplied by other countries.

5.3. The WTO TRIPs waiver and local production

The impact of IP rules imposed by the WTO had a major impact on ESA countries during the COVID-19 pandemic. A waiver was finally introduced in June 2022, but does it go far enough?

In as much as the waiver adopted provides some temporary reprieve to developing countries with no manufacturing capacity, it is limited in the following ways:

1. The waiver only covers the production and supply of COVID-19 vaccines and does not extend to therapeutics and diagnostics. For the latter, the decision states that “no later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics.” Therefore within six months, that is, in December 2022, WTO members “will decide” (and this is subject to further negotiations).
2. The provisions of this decision only apply up to five years from the date of the decision, that is until July 2027. Whilst the waiver provides the opportunity for the WTO General Council to extend this period, there is no certainty that this will be subject to negotiation. The wording of the waiver says, “The General Council may extend such a period taking into consideration the exceptional circumstances of the COVID-19 pandemic.” Essentially, this means that the extension of the waiver will depend on members’ agreement, given the prevailing situation and assuming that they agree that the ‘exceptional circumstances’ still apply in 2027.
3. The decision only applies to ‘eligible’ members, classified as all developing countries. However, the decision goes further to say “Developing country Members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision.”
4. The decision does not completely remove the obligation to pay royalties to the patent holder. Paragraph 2 (d) of the waiver states that “determination of adequate remuneration under Article 31(h) may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines in order to support manufacturers in eligible Members to produce and supply these vaccines at affordable prices for eligible Members. In setting the adequate remuneration in these cases, eligible Members may take into consideration existing good practices in instances of national emergencies, pandemics, or similar circumstances.”

For the region, the current situation raises some critical technology needs beyond EHPs including vaccines:

- To continue to secure and improve the supply of technologies and outreach of the services needed for prevention of COVID-19. This includes the various reagents and kits for antigen and antibody testing to test, trace and prevent onward infection and identify cases needing treatment or other forms of protection.
- To ensure the availability of infection control measures and PPE for health workers and other frontline workers to reduce their risk of exposure.
- To ensure the supply of oxygen, ventilation equipment, medicines and other care resources and health workers for treatment of cases and prevention of mortality (EQUINET, 2020).

Satisfying these needs will also prepare the region to respond to other future pandemics, as well as better cater for the needs of citizens with regard to the rising numbers of noncommunicable diseases and the more complex disease patterns they generate.

In summary, ESA countries can use the provisions of the waiver to pool resources to establish regional vaccine manufacturing plants and associated R&D. A regional approach is critical, as a larger regional market is essential for the development and sustainability of an effective manufacturing sector that can produce EHPS that respond to the currently unmet needs of people in the region. Pooling resources and capacities also shares risk and minimises any potential economic impact.

On the obligation to pay royalties when using the waiver, there are provisions in in Article 44.2 of the TRIPs agreement which state that member countries may limit the remedies available against such use to payment of remuneration. ESA countries may use this option in the application of the waiver by using their own laws and legal systems to limit compensation, thus avoiding high royalty payments.

6. Conclusion

Local production of EHPs is a critical issue in the COVID-19 response within the ESA. Local production in its broad sense involves the following:

- Innovation and creativity, unlocking value in people.
- Research and Development.
- Skills development and the promotion of programmes within educational institutions that respond to local needs and to the needs of local industry and people.
- Development and application of standards, quality assurance and metrology.
- Application of technology and technological transfer.
- Infrastructural investment.
- Market development.
- Promotion of employment creation.
- Improved product safety guarantees and
- Enhancement of the application of indigenous knowledge that is suited to local conditions;

It can increase affordability, promote stable and reliable access; and national self-determination.

There are economic, social and political incentives for investment in local production. Access to EHPs affects the entire population, whether treated in the public or private sector. Thus, any attempt to look at EHP production in the region must consider the public-private mix in provision and financing to understand both the impact on the health system as well as on households. It is not simply about access to care and EHP. It also has an impact on employment, incomes and reducing poverty and on economic and social development, with the health system as both catalyst and vehicle for economic transformation. It is on this foundation that the strategic imperative of access to and local production of EHP is built.

This report has mapped the legislative, regulatory, health system, market structure, supply-chain and broader socio-economic dynamics that shape current EHP discussions and the challenges ESA countries face. These will feed into broader regional discussions around the challenges of local production in the region.

Government initiatives to support innovation hubs at institutions of higher learning in Zimbabwe, and support to industries to manufacture PPE in Uganda and Kenya, are for example, fundamental steps in the quest to establish local production. The evidence provided regarding the manufacture of PPE, sanitisers, PCR tests and political will to buy locally produced PPE and other related EHPs, points to a positive development in encouraging local production.

In terms of IPR and technology transfer, the decision by the Governments of Kenya and Zimbabwe to support the proposal by South Africa and India on the TRIPs waiver at the WTO was an essential step in the reform of the IPR regime for technology transfer, innovation and development. Kenya and South Africa are already some of the six countries earmarked for mRNA technology transfer for the manufacture of vaccines.

The following recommendations are proposed.

In the short to medium term:
Production of APIs is central to local production of EHPs. ESA countries should engage with multinational corporations holding patents and licenses to build and shape relationships, partnerships and secure APIs in a way that ensures local production is profitable, rather than becoming a net drain on the health system.

ESA countries should support their local pharmaceutical sectors through measures such as restricting importation of locally produced medicines and raising import taxes on imported pharmaceutical products that can be manufactured locally;

ESA countries can strengthen measures to exempt duty and VAT on imported pharmaceutical raw and packaging materials to stimulate local production. ESA countries can also provide state incentives to companies that utilise local resources for local medicines production;

On the **TRIPs waiver**, ESA countries should use the provisions of the waiver to pool resources to carry out the associated R&D and to establish regional vaccine manufacturing plants with a regional approach in mind. This is critical as larger regional markets are essential for developing and sustaining a manufacturing sector that can produce EHPS to respond to currently unmet needs of people in the region. Pooling resources and capacities also shares risks and minimises the potential economic impact.

On the obligation to pay royalties when using the waiver, there are provisions in in Article 44.2 of the TRIPs agreement which state that member countries may limit the remedies available against such use to payment of remuneration taking into account the economic value of the authorisation as per Article 31 (h). ESA countries may use this option in the application of the waiver by using their own laws and legal systems to limit compensation, thus avoiding high royalty payments.

In the longer term:
ESA countries should: ***m***ake resources available for R&D to promote innovation and production of high-tech EHPs; and create a system that links industry and academic institutions to ensure relevant skills development in the pharmaceutical sector within the region.

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Acronyms

ADB	African Development Bank
AfCFTA	African Continental Free Trade Agreement
APIs	Active Pharmaceutical Ingredients
ART	Antiretroviral Therapy
AU	African Union
EAC	East African Community
AU CDC	African Union Centres for Disease Control
EHPs	Essential Health Products
ESA	East and Southern Africa
KEBS	Kenya Bureau of Standards
IPRs	Intellectual Property Rights
mRNA	Messenger ribonucleic acid (vaccine)
PPE	Personal Protective Equipment
R&D	Research and development
SADC	Southern Africa Development Community
OGIL	Open General Import License
PCR	Polymerase Chain Reaction
PPE	Personal Protective Equipment
TRIPs	Trade Related Aspects of Intellectual Property Rights
UNECA	UN Economic Commission for Africa
UNIDO	United Nations Industrial Organisation
WHO	World Health Organization
WTO	World Trade Organization

Equity in health implies addressing differences in health status that are unnecessary, avoidable and unfair. In southern Africa, these typically relate to disparities across racial groups, rural/urban status, socio-economic status, gender, age and geographical region. EQUINET is primarily concerned with equity motivated interventions that seek to allocate resources preferentially to those with the worst health status (vertical equity). EQUINET seeks to understand and influence the redistribution of social and economic resources for equity-oriented interventions. EQUINET also seeks to understand and inform the power and ability people (and social groups) have to make choices over health inputs and their capacity to use these choices towards health.

EQUINET implements work in a number of areas identified as central to health equity in east and southern Africa, including

- Protecting health in economic and trade policy, in extractives
- Local production of health technologies
- Urban health and wellbeing
- Building universal, participatory, primary health care oriented health systems
- Equitable, health systems strengthening responses to pandemics
- Fair Financing of health systems
- Promoting public health law and health rights
- Social empowerment and action for health
- Monitoring progress on equity and equity analysis

EQUINET is governed by a steering committee involving institutions and individuals co-ordinating theme, country or process work in EQUINET from the following institutions:
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