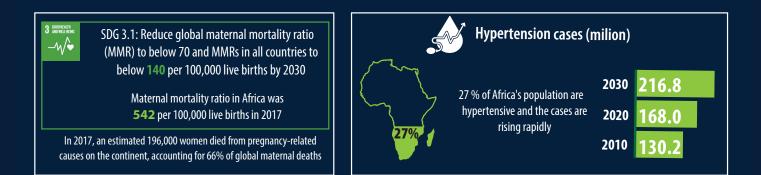
Mapping and Demand Analysis of Essential Medical Products and Technologies for Maternal, New-Born, and Child Health and Hypertension in Africa

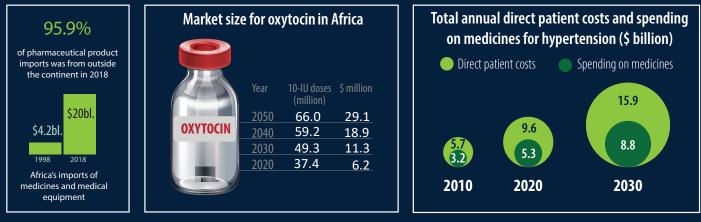


A Report for the Africa Investment Summit on Health

September 2021

AT A GLANCE





Essential Medicines for MNCH and Hypertension: Prices in African Countries vs. Global Median Prices

| Oxytocin 10-IU dose (\$/ml) | | Global: 0.1664 Hydrochlorothiazide 25 mg (\$/tablet | | (\$/tablet) | Global: 0.0237 | |
|--|---------------------------------|---|-----------------------------|-----------------------------|------------------|----------------|
| A | DRC: South Africa: Sudan: | 0.0710 0.3949 0.1884 | | South Africa: Sudan: | 0.0077 0.0859 | |
| Misoprostol 2 | 2 00 mcg (\$/tab | -cap) | Global: 0.1664 | Hydralazine 20 mg (\$/ampou | ıle) | Global: 2.2290 |
| | South Africa: | 0.3150 | | Sudan: | 2.9262 | |
| Amoxicillin 500 mg (\$/tablet) | | Global: 0.0299 | Captopril 25 mg (\$/tablet) | | Global: 0.0076 | |
| 99999999999999999999999999999999999999 | DRC: South Africa: | 0.0206 0.0343 | | South Africa: Sudan: | 0.0090 0.0388 | |
| Oral Rehydra | tion Solution | (\$/packet) | Global: 0.1664 | Losartan 50 mg (\$/tablet) | | Global: 0.0181 |
| | Nigeria: | 0.1200 | | South Africa: | 0.0194 | |

LEVERAGING THE AFCFTA TO BOOST INTRA-AFRICAN PHARMACEUTICALS TRADE:

Efforts to increase local pharmaceutical production in Africa have been hampered by small, fragmented markets and policy incoherencies. These are areas which the AfCFTA can help remedy in order to boost intra-regional trade of pharmaceuticals in Africa. It is important that trade negotiators ensure that the pharmaceutical and medical supplies sector is included as a priority sector for liberalization under the trade in goods negotiations. Experiences from other countries show that this can also attract investments to the sector and thereby lead to investments in training and skills development, accelerated technology transfer agreements, and job creation.

OPPORTUNITIES IN MAKING GENERICS: Producing off-patent drugs presents a unique opportunity for Africa to develop essential industrial capabilities while reducing risks. The technical requirements and production unit economics are lower for generics than for drugs under patents. Some countries with thriving pharmaceutical industries today — India and Brazil, for example — got their start by taking advantage of relatively lax intellectual property rights to produce generics for their large domestic markets. Africa may be able to do the same. A healthy generic industry can then serve as a platform to develop manufacturing experience and to train the workforce for increasingly more complex products over time.

REGULATORY STANDARDS: Introducing a continental set of regulations and standards in Africa's pharmaceutical market to assure the quality of medical products and ensure that local manufacturers adhere to such standards can have a positive impact on both the quality and the availability of the products that are needed specifically in Africa. The ratification of the African Medicines Agency (AMA) is an important step towards harmonizing rules and regulations to help fight informal markets and tackle the challenge of low-quality drugs through a coordinated monitoring mechanism of drug manufacturing.

SEQUENCING OF PHARMACEUTICAL MANUFACTURING: Sequencing the development of the pharmaceutical value chains (VC) in Africa could help ensure stable and long-term expansion. The VC steps can be prioritized by identifying the steps which will have the most immediate impact on cost, time, and capacity. Scaling up existing production of APIs in Africa of generic medicines for MNCH and hypertension will contribute to cheaper medicines and better access. Other dimensions of the value chains can be sequenced to the latter stages of the development of pharmaceutical manufacturing in Africa. This includes the stage of research and development (R&D) which is a highly costly and complex process.

1. INTRODUCTION

The World Health Organization (WHO) identifies "equitable access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost-effectiveness" as one of the six "building blocks" of a well-functioning health system.¹

Such access remains largely out of reach in Africa, partly due to limited local production capacity. Africabased manufacturers can meet less than two percent² of demand for medicines and one percent³ of that for vaccines on the continent. In 2017, only 37 African countries were able to produce medicines locally.⁴ Of these, South Africa had some capacity to make active pharmaceutical ingredients while most countries had to import such ingredients.⁵ Currently Africa, a continent of 1.2 billion people, is home to approximately 375 pharmaceutical manufacturers.⁶ China and India, geographies with comparable populations, count 5,000 and 10,500 drug makers, respectively.⁷ All countries in Africa are net importers of pharmaceutical products and, in 2018, 95.9 percent of imports are from outside the continent.⁸ Africa's imports of medicines and medical equipment rose sharply from \$4.2 billion in 1998 to \$20 billion in 2018.⁹ This translates to an average annual growth rate of 18.8 percent over 20 years. The demand for medicines and medical equipment underpinning this high growth rate is likely to be sustained, even when controlling for price inflation, given the demographic profile and prospects of the African population.

The problems with this supply-demand mismatch became most evident during the slow roll-outs of COVID-19 vaccines in Africa. First, global manufacturing constraints mean that high-income countries have bought up the vast majority of vaccines produced to date as well as a significant share of future supplies, leaving lowand middle-income countries to scramble for the small number of doses that remain. Second, new waves of infections and more transmissible variants have led major vaccine manufacturing countries to halt exports to reserve doses for domestic use, further delaying deliveries to Africa.¹⁰ This situation is likely to get worse as some countries insist on booster shots before every deserving person everywhere gets vaccinated.

Recognizing these facts, there is now a consensus and a singular collective resolve among African governments, regional organizations, the private sector, and the international community to expand the production of medicines and vaccines for Africans in Africa based on the grounds of health security and regional supply chain resilience. Robust local manufacturing can contribute significantly to Africa's response to current health priority areas as well as the continent's preparedness for future health crises. It can also be a powerful tool to develop medical solutions that are more suitable to local contexts.

This report maps out the essential medicines and technologies required for the diagnosis, prevention, and treatment of diseases in two important health areas: maternal, new-born, and child health (MNCH) and hypertension. It also seeks to estimate the market sizes for these medical products in Africa. The report conludes with an anylsis of what can be done to expand on-the-ground production of these products to increasingly meet the demand on the continent.

2. METHODOLOGY

The mapping and market sizing exercises in this report are limited to two areas of health priorities for Africa, MNCH and hypertension, for two reasons: first, the high burden of disease in these areas and, second, the high associated economic costs.

In 2017, an estimated 196,000 women died from pregnancy-related causes on the continent¹¹, accounting for 66 percent of global maternal deaths.¹² In the same year, maternal mortality ratio in Africa was 542 per 100,000 live births¹³ – almost three times the global average and significantly higher than the Sustainable Development Goals target 3.1 of reducing maternal mortality in all countries to below 140 per 100,000 live births by 2030. In 2017, 2.8 million children under the ages of five died in Africa, a near-30-percent drop from 1990 but still approximately 52 percent of the global total.¹⁴

Africa already has the highest prevalence of hypertension (27 percent) among WHO's reporting regions.¹⁵ And the cases are rising rapidly: it is estimated that 216.8 million Africans will be hypertensive in 2030.¹⁶ Urbanisation and unhealthy lifestyles are key contributors to this rise and, if current trajectories continue, noncommunicable diseases are set to kill more people in Africa than infectious diseases by 2030.¹⁷

This heavy burden of disease comes with proportionately high economic costs. A study estimated that the total expected non-health GDP loss from under-five child deaths was \$150.3 billion in purchasing power parity terms in the 47 countries that made up the WHO's AFRO region in 2013, a cost equivalent to six percent of their combined GDP that year.¹⁸ A 2009 study placed the direct healthcare costs associated with cardiovascular diseases at \$9 billion a year in Africa.¹⁹ On the other hand, improvements in health can bring significant economic benefits. From 1965 to 1990, between 30 to 50 percent of Asia's economic growth was attributed to better reproductive health, lower fertility rates, and reduced child mortality.²⁰ According to an analysis by the UN Economic Commission for Africa, reducing maternal mortality ratios by 125 deaths per 100,000 live birth and under-five mortality ratios by 50 deaths per 10,000 could each increase GDP growth by one percent.²¹

The scope for the mapping of essential medical products and technologies in this report covers medicines, diagnostics, and medical devices. This mapping exercise is unable to exhaustively list all the medical products and technologies associated with the two areas of focus. Instead, the lists we present below prioritise products and technologies that are considered essential, i.e. those that all well-functioning health systems should have *at a minimum*. This requires a certain degree of value judgement. To do this, our research started with a general literature search. As much as possible, however, we followed expert opinions given in documents such as the WHO Model Lists of Essential Medicines²² or by specialised bodies such as the UN Commission on Life-Saving Commodities for Women and Children.²³ These instruments identify and endorse medicines based on safety, efficacy, cost-effectiveness, and their potential to save lives if widely accessible and properly used. We offer a short description of the clinical purpose of each essential medical product and technology as well as analysis of its accessibility, affordability, and availability in Africa.

For the subsequent market sizing section, we started by conducting desk research for data on production, consumption, trade, and spending on medicines and other medical solutions in the two chosen areas. Most of these data come from market research companies, pharmaceutical trade groups, academic studies, and national and international statistical sources. We then estimated the market values for a few specific products. Where possible, we present data for the whole of Africa and for the entire areas of MNCH and hypertension. Otherwise, we provide relevant information for specific countries or product types only. This study has some limitations due to severely limited data. Findings should therefore be interpreted carefully. The adopted approach means that the results from our attempts to quantify the market sizes for MNCH and hypertension in Africa are necessarily incomplete and are informative rather than authoritative.

3. MAPPING OF ESSENTIAL MEDICAL PRODUCTS AND TECHNOLOGIES

3.1. THE MATERNAL, NEW-BORN, AND CHILD HEALTH LIST

Medicines, devices, equipment, and diagnostics for MNCH cover a broad range with thousands of products. In order to provide an effective presentation of essential products within this area, this report covers the essential medicines identified by the UN Commission on Life-Saving Commodities for Women and Children²⁴ within maternal health commodities, new-born health commodities, and child health commodities.



OXYTOCIN



Treatment: Oxytocin is a uterotonic medicine via injection and is used for prevention and treatment of postpartum hemorrhage (PPH) which is defined as excessive bleeding after childbirth. Oxytocin is recommended by WHO as the first-line medicine for the prevention and treatment of PPH and is also listed as the safest and most effective uterotonic medicine for the prevention and treatment of PPH²⁵.



Price: In 2015, the price of oxytocin in a 10-IU dose in Africa where country information exists was \$0.071/ml in DRC, \$0.1884/ml in Sudan, and \$0.3949/ml in South Africa. The global median price of oxytocin in 10-IU dose was \$0.1664/ml.²⁶



Availability: In a study on the availability and quality of oxytocin in eight African countries (Ghana, Zimbabwe, Burkina Faso, Kenya, Madagascar, Nigeria, Tanzania, and Uganda), two key issues were identified regarding quality of the active pharmaceutical ingredient (API) content and the sterility of the samples. The proportion of failed oxytocin samples in the countries was 57.5 percent.²⁷ Another study identifies cold chain supply as a significant challenge in ensuring availability of oxytocin.²⁸



MISOPROSTOL



Treatment: Misoprostol serves two distinct purposes: 1) for gastroprotection and healing of peptic and duodenal ulcers and 2) for a variety of obstetric and gynecological indications, including medical abortion, medical management of miscarriage, induction of labor, cervical ripening before surgical procedures, and prevention and treatment of PPH. Misoprostol is the second-line medicine recommended by the WHO for the prevention and treatment of PPH only when oxytocin use is not feasible. It is recommended for use of women giving birth outside of a health facility, as it is administered by pill rather than by injection.²⁹



Price: In 2015, the price of misoprostol 200 mcg capsules/tablets bought by the South African Department of Health was \$0.3150/tablet. No other country information was listed. However, the global median price was lower at \$0.2000/tablet.³⁰



Availability: There are now many generic misoprostol products available in low-income countries. In spite of availability and low prices, significant problems with misoprostol finished products exist when analyzed for content and purity. The active ingredient degrades rapidly between three months and one year. Because of this rapid degradation, pre-shipment testing may be of little value for an inappropriately manufactured or packaged product.³¹ A WHO study on the quality of misoprostol revealed that 40 percent of the sample collection were below 90 percent of labelled content of which 14 percent contained no misoprostol at all.³²



MAGNESIUM SULFATE



Treatment: Magnesium sulfate treats pre-eclampsia and eclampsia which is the secondleading cause of maternal death in low- and middle-income countries. Magnesium sulfate is recognized by WHO as the safest, most effective, and lowest-cost medicine for treating pre-eclampsia and eclampsia.³³



Price: In 2015, the price for magnesium sulfate of 50% strength via injection in Africa where country information exists was \$0.0095/ml in DRC, \$0.0599/ml in Sudan, and \$0.1705/ml in South Africa. The global median price was \$0.1152/ml.³⁴



Availability: The market for magnesium sulfate is small as it is rarely globally manufactured because its low-cost leaves little profit-based incentive for pharmaceutical companies to produce it. In Nigeria, where eclampsia is responsible for as many as 40 percent of maternal deaths in the northern regions, there are no domestic manufacturers of the drug.³⁵ However, manufacturing of magnesium sulfate exists in South Africa and East Africa. A study on the quality of magnesium sulfate in Nigeria reveals a high quality of the available drug where only 4 out of 160 magnesium sulfate samples failed, indicating a very stable quality of the product.³⁶



GENTAMICIN



Treatment: Gentamicin injection is the first-line drug recommended by WHO for the treatment of community acquired pneumonia, complicated severe acute malnutrition, and sepsis in neonates and children. Besides being presented for injection, gentamicin is also available in eye drops for ophthalmological infections, in ear drops for ear infections, and as a topical ointment for skin infections.³⁷



Price: In 2015, the price of gentamicin 40mg/ml in Africa where country information exists was \$0.0284/ml in DRC and \$0.1297/ml in South Africa. The global median price was \$0.0616/ml.³⁸



Availability: Gentamicin is available as a generic drug. In spite of this, the availability of gentamicin in relatively low. A study on maternal and child health services in eight African countries indicated that, on average, 42 percent of health facilities offer maternal gentamicin injection with the highest proportion in Burkina Faso at 68 percent and the lowest in the DRC at 11 percent. The average proportion of health facilities which offer gentamicin injection for children is 43.8 percent with the highest in Benin at 71 percent and the lowest in Zimbabwe at 0 percent.³⁹



CHLORHEXIDINE

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Price: In 2015, the price of chlorhexidine 7.1 percent purchased in DRC was \$0.026/g.⁴¹ It was not possible to identify a global median price.

Treatment: Chlorhexidine is a broad-spectrum antiseptic which is applied widely to avoid infections. This includes applications in wound care, hand washes, preoperative body shower,

oral hygiene, and particularly for neonatal care such as umbilical cord care.⁴⁰



Availability: Chlorhexidine 7.1 percent is a generic drug and is manufactured in Africa in Kenya and Nigeria. In 2020, the West African Health Organization (WAHO) announced the prequalification of chlorhexidine 7.1 percent for umbilical cord care manufactured by a Nigerian company which extends through 2025 to all member countries of ECOWAS.⁴²



AMOXICILLIN



Treatment: Amoxicillin is a broad-spectrum antibiotic of penicillin-class which is prescribed to children for treatment of pneumonia and other illnesses, including other bacterial infections of the ears, sinuses, throat, urinary tract, skin, abdomen, and blood. Amoxicillin is listed as first-line treatment for pneumonia in children under five by the WHO.⁴³



Price: In 2015, the price of amoxicillin 500 mg tablet or capsule in Africa where country information exists was \$0.0206/tablet in DRC and \$0.0343/tablet in South Africa. The global median price was at \$0.0299/tablet.⁴⁴



Availability: Amoxicillin is a generic drug and production of such antibiotics takes place in some African countries such as Ghana and Nigeria. However, challenges on quality of APIs and availability remains.⁴⁵ A study on maternal and child health services in eight African countries indicated an average percentage of health facilities which offer amoxicillin at 66 percent with the highest in Sierra Leone at 89 percent and the lowest in Uganda at 28 percent.⁴⁶



ORAL REHYDRATION



Treatment: Oral rehydration solution (ORS) is an oral powder-containing mixture of glucose sodium chloride, potassium chloride, and sodium citrate. After being dissolved in the requisite volume of water they prevent and treat dehydration due to diarrhea, including maintenance therapy. ORS is highly effective and affordable for treatment of childhood diarrhea that could prevent deaths in up to 93 percent of diarrhea cases.⁴⁷



Price: In 2015, the price of ORS in Africa where country information exists was \$0.1200/ packet in Nigeria.⁴⁸ The global median price was significantly lower at \$0.0561/packet.



Availability: ORS is a generic drug. Among the five UNICEF trusted manufacturers of ORS, two are based in Africa in Nigeria and Kenya. ORS is stable at ambient temperatures/ humidity and is unlikely to undergo any significant degradation as a result of heat/humidity if it its properly manufactured. A study on ORS availability in child health services in eight African countries indicated an average coverage of ORS in health facilities at 73.6 percent with the highest in Zimbabwe at 93 percent and the lowest in Mauritania at 49 percent.⁴⁹



ZINC



Treatment: Zinc supplements are recommended by WHO for the management of acute diarrhea in children. Zinc supplements to young children are preferred in the form of dispersible tablets or oral solution for the ease of administration and logistics.⁵⁰



Price: In 2015, the price of zinc sulfate 20 mg tablets/capsules for children in Africa where country information exists was \$0.02/tablet in Nigeria and \$ 0.0120/tablet in Uganda. The global median price was significantly lower at \$0.0094/tablet.⁵¹



Availability: Studies in eight African countries found that zinc sulfate is available on an average at 52.8 percent of health facilities with the highest availability in Zimbabwe at 95 percent and the lowest in Mauritania at 13 percent. A marked difference appears in availability of zinc in private facilities compared to public facilities where zinc was found to be available in 1 to 93 percent (median 55 percent) of private facilities versus public facilities where zinc was available in between 16-97 percent (median 66 percent).⁵² Two manufacturers in Africa in Nigeria and Kenya are approved by UNICEF as sources for procurement.⁵³

TECHNOLOGICAL AND RESUSCITATION DEVICES

One of the categories listed in the UN Commission on Life-Saving Commodities to end preventable deaths of women and children is neonatal resuscitation devices, an indispensable medical device to save new-borns from asphyxia at birth. Another report on essential devices for new-born care by UNICEF and NEST360° identifies neonatal healthcare technologies that are critical to address neonatal mortality in low-resource settings.⁵⁴ Most of such technologies are designed for high-resource settings and are either unavailable or unsuitable for use in low-resource settings. Therefore, these technologies are identified with the objective to particularly address neonatal mortality in the first week of life in Africa by ensuring the devices are of high quality, affordable, robust, and appropriate for comprehensive care delivery in low-resource settings.

NEONATAL RESUSCITATION SELF-INFLATING BAG WITH MASK



Treatment: A neonatal resuscitation bag with mask is the most standard neonatal device to ventilate a neonate with asphyxia which is defined as the failure to initiate and sustain breathing at birth. The device usually consists of three main parts: a bag, a pressure relief valve, and a facemask.⁵⁵



Price: The price for self-inflating bags with masks for neonatal resuscitation was not identifiable in Africa. However, according to sources the cost ranges between \$5⁵⁶ and \$15⁵⁷ in low-and middle-income countries.



Availability: Estimates from six African countries for the percentage of babies born in facilities with staff trained in bag-and-mask resuscitation indicate a small proportion of babies born at facilities with equipment for new-born respiratory support. Here, 45 percent of all babies were born in facilities and 15.2 percent of all babies were born at facilities with equipment for new-born respiratory support.⁵⁸



SUCTION MACHINE



Treatment: When the infant still has fluid in the airway and is unable to breathe enough in the first few minutes of life, suction can assist in removing the fluid and clear the airway to allow the new-born to breathe easily.⁵⁹



Price: The price of a suction machine at the Africa Medical Supplies Platform is \$105.60



Availability: A study on availability of suction machines in nine African countries showed limited availability of such instruments in public hospitals with a few more reported in private health facilities. High costs and no repair were identified as the major reasons for limited availability of this equipment.⁶¹



PHOTOTHERAPY LIGHT



Treatment: Blue light phototherapy present morbidity and mortality for severe cases of neonatal jaundice. The blue light breaks down bilirubin in the blood and allow the infant to excrete the excess bilirubin before it can accumulate and cause permanent brain damage or death.⁶²



Price: Phototherapy light is extremely price sensitive depending on the geography. Current brands sell these devices for \$2,000.⁶³



Availability: The high price of phototherapy light limits access to this technology in Africa.⁶⁴ Providing low-cost, effective, and practical solutions will be key so ensure a wide availability of phototherapy light in Africa.



RADIANT WARMER



Treatment: The radiant warmer provides heat using an overhead heating source to treat and prevent hypothermia in neonates requiring intensive thermal care.



Price: Finding such an instrument on the market for below \$1,000 is not common and radiant warmers sold in Africa have been identified to cost up to \$3,500.⁶⁵ Product developers have noted that that pricing can be reduced when the number of units purchased increases, unlocking economies of scale.⁶⁶



Availability: According to Target Product Profile for New-Born Care the effective price in lowresource settings for a radiant warmer is between \$500 and \$1,500 ex-works. The high price is therefore a main barrier to ensure wide access to radian warmers in Africa. Limited electrical infrastructure leads to increased demand for back-up batteries which further challenges the availability and utility of radiant warmers.

3.2 THE HYPERTENSION LIST

Hypertension can only be diagnosed through accurate measurement of a person's blood pressure. Most major guidelines recommend that hypertension is diagnosed when a person's systolic blood pressure (SBP) is 140 mmHg and/or their diastolic blood pressure (DBP) is 90 mmHg following repeated examination.⁶⁷ While the diagnosis can be made on a single office visit if the BP is 180/110 mmHg and there is evidence of cardiovascular disease (CVD), two to three office visits with 1 to 4 week intervals are usually required to make an accurate diagnosis.⁶⁸

To ensure that hypertension is diagnosed in a timely and accurate manner, it is necessary that local medical facilities stock the right medical equipment. According to the WHO technical package for cardiovascular disease management in primary health care, the most essential equipment for diagnosing hypertension is an automated blood pressure device or sphygmomanometer, in addition to a stethoscope, scale, and tape measure.⁶⁹

AUTOMATED BLOOD PRESSURE DEVICE OR SPHYGMOMANOMETER

A device capable of accurately measuring blood pressure levels is arguably the most crucial equipment for diagnosing hypertension. This can come in the form of an automated blood pressure device or a mercury sphygmomanometer.

Price: According to WHO figures for a typical district hospital in Kenya, the unit price of a sphygmomanometer is around \$16.50.⁷⁰

Availability: A 2015 study of health facilities in the Mukono and Buikwe Districts in Uganda found that one-tenth of the facilities lacked functioning blood pressure devices.⁷¹ To get accurate blood pressure measurement results, it is essential to calibrate the sphygmomanometer before use. Out of 126 medical facilities surveyed in Uganda, only one had ever calibrated their blood pressure devices.⁷²



STETHOSCOPE

A stethoscope can be used to listen to the heart and lungs of a patient in order to examine whether there are irregularities in the pulse rate or breathing patterns, as well as listen for extra heart sounds or basal crackles.⁷³

Price: According to WHO figures for a typical district hospital in Kenya, the unit price of a stethoscope is around \$5.50.⁷⁴

Availability: A study in rural Uganda found that nearly one-third of the medical facilities surveyed did not have stethoscopes.⁷⁵



TAPE MEASURE

Tape measure can be wrapped around the patient's arm to measure the cuff size needed. It can also be used to measure the patient's body in order to make judgements about their general physical health.

Price: According to WHO figures for a typical district hospital in Kenya, the unit price of a tape measure is around \$4.⁷⁶



WEIGHING SCALE

A weighting scale can help inform whether a patient is overweight or obese. Overweight or obesity is one of the most common comorbidities of hypertension, with 40 percent of hypertensive patients suffering from one or the other.⁷⁷

Price: According to WHO figures for a typical district hospital in Kenya, the unit price of a weighing scale for adults is around \$90.⁷⁸

MEDICINES FOR TREATMENT

Ensuring access and availability of the correct medicines and health products is essential for the effective management of hypertension. The four most essential medicine groups used in treating hypertensive patients are thiazide or thiazide-like diuretics, calcium channel blockers (CCB), angiotensin converting enzyme inhibitors (ACE-I), and angiotensin receptor blockers (ARB).⁷⁹

In a meta-analysis comparing the results of thirty-two studies of 2,860 participants across Africa, CCBs were found to be the most efficacious first-line agent for treating hypertension. The study suggests that CCBs used in combination with ACE inhibitors or diuretics to be the superior method of treating hypertensive patients across Africa.⁸⁰ A 2015 study of health facilities in the Mukono and Buikwe Districts in Uganda found that only about half of the facilities had anti-hypertensive medicines in stock, with 46 percent stocking thiazide diuretics and 48.8 percent stocking calcium channel blockers.⁸¹

Hypertensive patients are prone to having several common comorbidities which may present a risk to their cardiovascular health and affect the preferred treatment strategy. More than 50 percent of hypertensive patients have additional cardiovascular risk factors and the prevalence of comorbidities tends to increase with the age of the patient.⁸² The most common comorbidities for hypertensive patients include diabetes (15-20 percent), lipid disorders (30 percent), overweight/obesity (40 percent), and Metabolic Syndrome (MS) (40 percent).⁸³ A lack of essential medicines for treating hypertension can have potentially serious consequences if combined with a comorbidity. It is therefore essential to stock all the medicines necessary for treating hypertension.⁸⁴



THIAZIDE DIURETIC



Treatment: Thiazide diuretics were the first tolerated medicine which proved effective at reducing cardiovascular morbidity and mortality in hypertensive patients. The compound treats hypertension by lowering the blood pressure of patients.⁸⁵

Generic names: hydrochlorothiazide, chlorthalidone, indapamide, bendroflumethiazide, metolazone, chlorothiazide.⁸⁶



Price: In 2015, the price of hydrochlorothiazide 25 mg tablets was \$0.0077/tablet in South Africa and \$0.0859/tablet in Sudan. The global median price was \$0.0237/tablet.⁸⁷ The unit price of hydrochlorothiazide 12.5 mg tablets in South Africa was \$0.0077.

Availability: WHO data suggest that thiazide diuretics are available in the public health sectors of most African countries, except for in Burkina Faso, Congo, Gabon, Gambia, and Niger.⁸⁸



CALCIUM CHANNEL BLOCKER (CCB)



Treatment: Calcium channel blockers are used to lower blood pressure, as well as other conditions such as chest pain and irregular heartbeat. It does this by preventing calcium from entering the cells of the heart and arteries, thereby allowing blood vessels to relax and open.⁸⁹ Along with diuretics, calcium blockers have been found to be more effective than beta blockers, angiotensin-converting enzyme inhibitors, or angiotensin II receptor blockers for treating hypertension in patients of African ancestry.⁹⁰

Generic names: hydralazine, nifedipine, verapamil, isradipine, diltiazem, nicardipine, felodipine, amlodipine, nisoldipine, levamlodipine, clevidipine.⁹¹



Price: In 2015, the price of nifedipine 10 mg tablets in South Africa was \$0.0403/tablet, while verapamil 40 mg cost \$0.0275/tablet.⁹²⁹³ Hydralazine 20 mg ampoules had a unit cost of \$ 2.9262/ampoule in Sudan.⁹⁴ In South Africa, hydralazine 25 mg tablets had a unit cost of \$0.0300/tablet, while 50 mg tablets had a unit cost of \$0.0491.⁹⁵⁹⁶



Availability: CCBs are generally available across the public health sectors of African countries, with exceptions including Burundi, Chad, Congo, Cote d'Ivoire, Eritrea, Eswatini, Gabon, Gambia, Liberia, Madagascar, Malawi, Mali, Mauritania, Niger, Sierra Leone, South Sudan, and Zimbabwe.⁹⁷



ANGIOTENSIN-CONVERTING ENZYME INHIBITOR (ACEI)



Treatment: Angiotensin-converting enzyme inhibitors lower blood pressure by helping to relax veins and arteries. They achieve this by preventing an enzyme from producing angiotensin II, which is a substance that narrows the blood vessels and thereby causes high blood pressure.⁹⁸ While both ACEIs and ARBs are effective treatments of hypertension, a 2014 South African study found it more cost-beneficial to treat chronic hypertensive patients with ACEIs rather than ARBs.⁹⁹Another study from South Africa made a similar finding and recommends only prescribing ARBs to patients that are intolerant to ACEIs.¹⁰⁰

Generic names: captopril, enalapril, lisinopril, moexipril, fosinopril, quinapril, ramipril, benazepril, trandolapril, perindopril.¹⁰¹



Price: In 2015, the price of captopril 25 mg tablets was \$0.0090/tablet in South Africa and \$0.0388/tablet in Sudan. The global median price was \$0.0076/tablet.¹⁰² The unit price for captopril 50 mg tablets was \$ 0.0776/tablet in Sudan.¹⁰³ The unit price of enalapril 10 mg tablets was \$ 0.0102/tablet in South Africa and \$ 0.0195/tablet in Sudan.¹⁰⁴ In South Africa, the unit price of enalapril 20 mg was \$0.0134/tablet, while the unit price of enalapril 5 mg was \$ 0.0082/tablet.¹⁰⁵¹⁰⁶



Availability: While ACEIs are available in the public health sectors of most African countries, there are notable exceptions. These include Benin, Burundi, Chad, Congo, Cote d'Ivoire, Gabon, Gambia, Liberia, Malawi, Niger, Nigeria, Sao Tome and Principe, Sierra Leone, South Sudan, and Sudan.¹⁰⁷



ANGIOTENSIN RECEPTOR BLOCKER (ARB)



Treatment: Angiotensin II receptor blockers help lower blood pressure by relaxing veins and arteries in order to make it easier for the heart to pump blood. This is achieved by blocking the action of angiotensin II, which is a chemical that narrows the blood vessels.¹⁰⁸ It is worth noting that ACEIs and ARBs are not to be used in conjunction; rather, the relevant health professional will determine which of the medicines should be used.



Generic names: eprosartan, olmesartan, valsartan, candesartan, telmisartan, azilsartan, losartan, irbesartan.¹⁰⁹

Price: In 2015, the average price of losartan 50 mg tablets in South Africa was \$0.0194/ tablet. This is slightly higher than the global median price of \$0.0181/tablet.¹¹⁰



Availability: More than half of African countries lack availability of ARBs in the public health sector. These include Benin, Burkina Faso, Burundi, Chad, Congo, Cote d'Ivoire, Djibouti, Eritrea, Eswatini, Ethiopia, Gabon, Gambia, Guinea, Malawi, Mozambique, Niger, Nigeria, Sao Tome and Principe, Senegal, Sierra Leone, South Sudan, Sudan, and Zimbabwe.¹¹¹

4. MARKET SIZING ANALYSIS

4.1 THE MATERNAL, NEW-BORN, AND CHILD HEALTH MARKET

According to one estimate, the global maternal and child healthcare market was valued at \$501 billion in 2020 and is expected to rise to \$1.76 trillion by 2030.¹¹² These include spending on pre-natal, birthing, post-natal, and fertility services. Among the key drivers for the market's rapid growth are rising adoption of mother and child services and the increased willingness and ability by pregnant women to pay out-of-pocket expenses.¹¹³

It is difficult to arrive at the total market size for MNCH in Africa due to the lack of data and inconsistent definition of what constitutes this market. We can, however, estimate the sizes of some of its components. For instance, a meta-analysis¹¹⁴ found that patient costs¹¹⁵ for a normal delivery in an African hospital ranged from \$5.6 to \$52.4 while patients pay significantly more for C-sections. In 2020, there were 43.7 million births on the continent.¹¹⁶ So at a minimum, out-of-pocket expenditure for birth-related services was between \$245 million and \$2.3 billion.

There are various estimates¹¹⁷ of the market sizes in Africa for essential MNCH drugs such as oxytocin and misoprostol, but most of them are outdated. Adopting the methodology of Schocken (2014)¹¹⁸, we can estimate the market size for oxytocin in Africa in 2020 and to extrapolate these figures into the future based on forecast number of births on the continent.

Oxytocin is used to induce labour and to prevent and treat postpartum haemorrhage (PPH).¹¹⁹ The market size and value for oxytocin can be estimated based on demographic and health system data (number of births, births taking place at health facilities, PPH prevalence); the recommended dosing regimen; availability of oxytocin at health facilities; and prices.

Oxytocin is a controlled substance and is only given to women giving birth at health facilities. Table 1 outlines the demographic and health system data between 2020 and 2050, when Africa's population is expected to double.¹²⁰

Table 1: Number of births and PPH cases in Africa

| Indiaatar | Year | | | | |
|---|------------|------------|------------|------------|--|
| Indicator | 2020 | 2030 | 2040 | 2050 | |
| 1. Total births ¹²¹ | 43,713,339 | 49,188,545 | 54,538,739 | 58,409,781 | |
| 2. PPH prevalence (%) ¹²² | 10.55 | 10.55 | 10.55 | 10.55 | |
| 3. Total PPH cases (1x2) | 4,611,757 | 5,189,391 | 5,753,837 | 6,162,232 | |
| 4. Facility-based births (%) ¹²³ | 59.90 | 70.20 | 76.03 | 79.12 | |
| 5. Total births at facilities (1x4) | 26,184,290 | 34,532,489 | 41,464,298 | 46,215,955 | |
| 6. Total PPH cases at facilities (3x4) | 2,762,443 | 3,643,178 | 4,374,483 | 4,875,783 | |

The recommended dosage regimen¹²⁴ for oxytocin is as follows and is summarised in Table 2:

- **Prevention:** 10 International Units (IUs) of oxytocin are given to all women giving birth at health facilities.
- **Treatment:** Among all women who have received one oxytocin prevention dose, approximately 2.85 percent develop severe PPH during childbirth; and about 6 percent of women giving birth at health facilities who have received one misoprostol prevention dose suffer from severe PPH. Both groups are given 40 IUs of oxytocin as treatment.
- In addition to PPH prevention and treatment, oxytocin is also given to about 10 percent of pregnant women at health facilities to **induce** labour (5 IUs) and 20 percent of women giving facility-based births to **augment** delivery (10 IUs).

Table 2: Dosing regimen for oxytocin

| Purpose | Dosage (IU) | 10-IU Doses Needed | Proportion of Facility- Based Births Requiring Oxytocin (%) |
|--|----------------|-----------------------|---|
| Prevention of PPH | 10 | 1 | 100 |
| Treatment of PPH after oxytocin prevention dose | 40 | 4 | 2.85 |
| Treatment of PPH after misoprostol prevention dose | 40 | 4 | 6 |
| Induction of labour | 5 | 0.5 | 10 |
| Augmentation of delivery | 10 | 1 | 20 |

The total addressable market for oxytocin comprises all women giving birth: in an ideal world, every single woman should be able to deliver at proper health facilities which, in turn, could give them access to oxytocin. But in reality, only a portion of pregnant women benefit from facility-based deliveries. Therefore, the serviceable addressable market for oxytocin is the number of women in this sub-segment discounted by the level of availability of oxytocin (only 89 percent of health facilities have regular availability for oxytocin).¹²⁵ We can then derive the actual market size for oxytocin in Africa – measured in the total number of 10-IU doses required annually – by multiplying the number of women in the serviceable addressable market with the number of doses recommended by the dosing regimen. This market size is given in Table 3.

Table 3: Market size for oxytocin in Africa (number of doses needed) – Base case

| | 2020 | 2030 | 2040 | 2050 |
|---|------------|------------|------------|------------|
| Prevention doses | 3,304,018 | 30,733,915 | 36,903,225 | 41,132,200 |
| Treatment doses (after oxytocin prevention doses) | 2,656,658 | 3,503,666 | 4,206,968 | 4,689,071 |
| Treatment doses (after misoprostol prevention doses) | 5,592,964 | 7,376,140 | 8,856,774 | 9,871,728 |
| Induction doses | 1,165,201 | 1,536,696 | 1,845,161 | 2,056,610 |
| Augmentation doses | 4,660,804 | 6,146,783 | 7,380,645 | 8,226,440 |
| Total 10-IU doses needed | 37,379,645 | 49,297,200 | 59,192,773 | 65,976,048 |

Table 4 shows the calculations for the market value for oxytocin, which is simply the product of the number of doses needed every year and the unit cost per dose. According to the latest International Medical Products Price Guide released by Management Sciences for Health (MSH) and the WHO in 2015, buyers pay a median price of \$0.1664 for a 10-IU dose of oxytocin.¹²⁶

Table 4: Market value of oxytocin in Africa (USD) – Base case

| | 2020 | 2030 | 2040 | 2050 |
|-----------------------------|------------|------------|------------|------------|
| Total 10-IU doses needed | 37,379,645 | 49,297,200 | 59,192,773 | 65,976,048 |
| Cost per 10-IU dose (\$)127 | 0.1664 | 0.2302 | 0.3185 | 0.4407 |
| Market value (\$) | 6,219,973 | 11,349,554 | 18,855,083 | 29,076,978 |

The analysis above shows that Africa requires 37.38 million doses of oxytocin worth approximately \$6.22 million today. The annual number of births on the continent is projected to increase over the foreseeable future. Over time, we can also expect the proportion of women giving births at health facilities to rise, which will drive greater access to essential MNCH medicines including oxytocin. These factors mean that the demand for oxytocin is set to grow to around 66 million doses valued at close to \$30 million by 2050. There is evidence, however, that some African countries pay significantly more – in some cases, by as much as 30 times – for medicines than the indicated global prices.¹²⁸ These estimated market values are, therefore, likely to be at the conservative end of the spectrum.

In an ideal scenario in which all pregnant women are able to deliver at health facilities and where 100 percent of facilities have regular availability of oxytocin, the theoretical demand for this critical PPH drug is higher than the estimates above. The number of annual doses needed in Africa and their market value in this scenario are summarised in Tables 5 and 6, respectively. In 2020, compared to the base case, the number of required oxytocin doses nearly doubles to 70 million doses worth \$11.67 million. The rising number of births as well as price increases (in line with inflation) then drive the demand for oxytocin up to approximately 94 million doses by 2050 with a market value of \$41 million.

Table 5: Market size for oxytocin in Africa (number of doses needed) – Ideal scenario

| | 2020 | 2030 | 2040 | 2050 |
|---|------------|------------|------------|------------|
| Prevention doses | 43,713,339 | 49,188,545 | 54,538,739 | 58,409,781 |
| Treatment doses (after oxytocin prevention doses) | 4,983,321 | 5,607,494 | 6,217,416 | 6,658,715 |
| Treatment doses (after misoprostol prevention doses) | 10,491,201 | 11,805,251 | 13,089,297 | 14,018,347 |
| Induction doses | 2,185,667 | 2,459,427 | 2,726,937 | 2,920,489 |
| Augmentation doses | 8,742,668 | 9,837,709 | 10,907,748 | 11,681,956 |
| Total 10-IU doses needed | 70,116,196 | 78,898,426 | 87,480,137 | 93,689,289 |

Table 6: Market value of oxytocin in Africa (USD) - Ideal scenario

| | 2020 | 2030 | 2040 | 2050 |
|--------------------------|------------|------------|------------|------------|
| Total 10-IU doses needed | 70,116,196 | 78,898,426 | 87,480,137 | 93,689,289 |
| Cost per 10-IU dose (\$) | 0.1664 | 0.2302 | 0.3185 | 0.4407 |
| Market value (\$) | 11,667,335 | 18,164,560 | 27,865,652 | 41,290,763 |

4.2 THE HYPERTENSION MARKET

Hypertension prevalence is rising globally, and in Africa in particular, as a result of population growth and ageing, improving living standards, rapid urbanisation, and changing lifestyles. As a result, hypertensive diagnosis, treatment, and management is a growing market worldwide. For diagnostics, the market for blood pressure monitoring devices was worth \$1.4 billion in 2020 and is expected to rise at double-digit compound annual growth rate (CAGR) from 2021 to 2028.¹²⁹ In the treatment segment, an estimate valued the global hypertensive drugs market at \$22.56 billion in 2018, with this number projected to increase at a 3.1 percent CAGR to \$28.80 billion by 2026.¹³⁰ Much of the market is accounted for by spending on major therapeutic categories including diuretics, ACE inhibitors, calcium channel blockers, vasodilators, and beta-adrenergic blockers.¹³¹ In addition to rising prevalence, the key driver behind the growth in these markets appears to be increased awareness among governments and patients of the importance of early diagnosis and treatment in saving lives.

Similar to the MNCH market, detailed data for the hypertension market in Africa is lacking, posing a challenge to any market sizing exercise. What we can do is use findings from studies of costs of hypertension care at country level to try to estimate the figures for the whole continent. This approach is necessarily imprecise but can yield some useful indicative results.

A 2017 survey of 212 patients in Kenya found that the mean annual direct costs of care for hypertension was \$304.8, with \$168.9 of that amount going towards paying for medicines.¹³² Kenya's GDP per capita (in current US dollars) was about the same as that for Africa (except North Africa) in 2017.¹³³ Hence, it is not unreasonable to assume that costs of hypertension care elsewhere on the continent were broadly comparable to those in Kenya. There were an estimated 130.2 million people with hypertension in Africa in 2010, a number that is projected to rise to 216.8 million by 2030 at a CAGR of 2.58 percent.¹³⁴ Not all people with hypertension know about their condition: the awareness rate¹³⁵ was only 33.7 percent in 2010.¹³⁶ And half of those who are aware receive treatment.¹³⁷

Table 7 presents estimates of the total annual direct patient costs and the total annual spending on medicines for hypertension in Africa from 2010 to 2030 based on the inputs described above and the following assumptions:

- The mean annual direct patient costs and the mean annual spending on medicines in Africa as a whole were the same as those in Kenya, i.e. \$304.8 and \$168.9 in 2017, respectively;
- For other years, these costs are adjusted by an inflation rate of 3.3 percent p.a.;¹³⁸
- The awareness rate remains 33.7 percent for the forecasting period; and
- The treatment rate remains 50 percent for the forecasting period.

Table 7: Total annual direct patient costs and total annual spending on medicines for hypertension in Africa (USD) – Base case

| Year | 2010 | 2020 | 2030 |
|---|---------------|---------------|----------------|
| 1. Hypertension cases | 130,200,000 | 167,972,402 | 216,800,000 |
| 2. Awareness rate (%) | 33.70 | 33.70 | 33.70 |
| 3. Number of people aware of hypertensive condition (1x2) | 43,877,400 | 56,606,699 | 73,061,600 |
| 4. Treatment rate (%) | 50 | 50 | 50 |
| 5. Number of people receiving treatment (3x4) | 21,938,700 | 28,303,350 | 36,530,800 |
| 6. Mean annual direct patient costs (\$)139 | 261.60 | 337.49 | 435.40 |
| 7. Mean annual spending on medicines (\$) ¹⁴⁰ | 144.96 | 187.02 | 241.27 |
| 8. Total annual direct patient costs (\$) (5x6) | 5,739,177,857 | 9,552,203,769 | 15,905,666,491 |
| 9. Total annual spending on medicines (\$) (5x7) | 3,180,272,769 | 5,293,199,530 | 8,813,868,341 |

Driven by a swift rise in the number of hypertension cases in Africa, direct patient costs are estimated to almost triple from \$5.74 billion in 2010 to close to \$16 billion in 2030. More than half of that amount is accounted for by spending on antihypertensive medicines: \$3.18 billion in 2010 and rising at a CAGR of 5.23 percent to \$8.81 billion in 2030.

There are potential upsides to these estimates as both the awareness rate and treatment rate of hypertension should increase alongside standards of living and access and quality of medical care. This is depicted in Table 8 in an ideal scenario where awareness and treatment rates are set to 100 percent. The direct patient costs in this scenario could increase almost six times to \$94.39 billion in 2030 compared to the base scenario of lower awareness and treatment rates (with estimated direct patient costs of \$15.9 billion in 2030).

Table 8: Total annual direct patient costs and total annual spending on medicines for hypertension in Africa (USD) – Ideal scenario

| Year | 2010 | 2020 | 2030 |
|--|----------------|----------------|----------------|
| 1. Hypertension cases | 130,200,000 | 16,972,402 | 216,800,000 |
| 2. Mean annual direct patient costs (\$) | 261.60 | 337.49 | 435.40 |
| 3. Mean annual spending on medicines (\$) | 144.96 | 187.02 | 241.27 |
| 4. Total annual direct patient costs (\$) (1x2) | 34,060,320,000 | 56,689,005,951 | 94,394,720,000 |
| 5. Total annual spending on medicines (\$) (1x3) | 18,873,792,000 | 31,414,198,622 | 52,307,336,000 |

5. ANALYSIS

Leveraging the AfCFTA to boost intra-African pharmaceuticals trade: Most African countries are heavily dependent on imports from outside Africa for essential pharmaceutical products: it is possibly the industry with the highest import dependency. All African countries are net importers of medical and pharmaceutical products.¹⁴¹ At the same time, Africa has one of the fastest growing pharmaceutical industries in the world, with countries such as South Africa, Nigeria, and Ghana leading the charge. Efforts to increase local pharmaceutical production in Africa have been underway for a long time, with the Pharmaceutical Manufacturing Plan for Africa (PMPA) having been adopted by the African Union in 2007. Among the challenges facing the African pharmaceutical markets, the PMPA lists "small fragmented markets", "fragmented and poor procurement and supply chain systems," and "policy incoherencies across trade, industry, health, and finance."¹⁴² These are all areas which the African Continental Free Trade Area (AfCFTA) can help remedy in order to boost intra-regional trade of pharmaceuticals in Africa. For this reason, it is important that trade negotiators ensure that pharmaceuticals are not restricted to the AfCFTA's exclusion lists, but that the medical supplies sector is included as a priority sector for liberalization under the trade in goods negotiations. Experiences from other countries show that this can also attract investments to the sector and thereby lead to investments in training and skills development, accelerated technology transfer agreements, and job creation.¹⁴³

Opportunities in making generics: In Africa's ambition to build robust local pharmaceutical manufacturing capacity, time horizon matters. It is useful to start by recognizing that innovation can come in two forms: the invention of new technologies and solutions and the adoption of existing ones. In some areas, African countries have to be patient for long-term investment in R&D to bear fruit. But where possible, they also need to look for immediate results through technology transfer and the implementation of existing patents and intellectual properties. Producing off-patent drugs presents a unique opportunity for Africa to develop essential industrial capabilities while reducing risks. The technical requirements and production unit economics are lower for generics than for drugs under patents. Some countries with thriving pharmaceutical industries today - India and Brazil, for example - got their start by taking advantage of relatively lax intellectual property rights in the mid-twentieth century to produce generics for their large domestic markets. Africa – with a 1.2-billion-strong continental market unlocked by the AfCFTA and ongoing discussions around reforms of the global intellectual property regime – may be able to do the same. Our analysis shows that many MNCH and antihypertensive drugs are available under generic formulations. Given the significant impact that improvements in these two areas can have on Africa's health and economies, they are good candidates for inclusion in a burgeoning African generic drug production push. A healthy generic industry can then serve as a platform to develop manufacturing experience and to train the workforce for increasingly more complex products over time.

Regulatory standards: The analysis identifies the lack of regulatory policies and standards as a key obstacle to access quality pharmaceuticals for hypertension and MNCH in Africa. These challenges typically result in poor quality of APIs and the packaging of final products as well as creating room for selling sham and counterfeit products. Introducing a continental set of regulations and standards in Africa's pharmaceutical market to assure the quality of medical products and ensure that local manufacturers adhere to such standards can have a positive impact on both the quality and the availability of the products that are needed specifically in Africa. In addition, along with the intra-African trade opportunities that are created through the AfCFTA, a common set of regulations and standards will further address the challenge of small and fragmented markets. This can help African pharmaceutical manufacturers to harness industrial synergies and produce medicines at competitive prices, strengthening the incentive for intra-African trade in this sector. Moreover, a stable regulatory environment can attract long-term financial support as harmonized regulatory standards are key to attracting investors. The ratification of the African Medicines Agency (AMA) is an important step towards harmonizing rules and regulations to help fight informal markets and tackle the challenge of low-quality drugs through a coordinated monitoring mechanism of drug manufacturing. AMA will be a key stakeholder in promoting a harmonized set of standards and regulatory policies for pharmaceutical products and medical equipment manufactured in Africa. With the large potential to improve two health areas with severe negative impacts in Africa, setting rules and standards for medicines and medical technologies to prevent, diagnose, and treat hypertension and MNCH diseases could be a starting point.

Sequencing of pharmaceutical manufacturing: In order to expand on-the-ground production of essential medicines and technologies to prevent, diagnose, and treat diseases within MNCH and hypertension, sequencing the development of the pharmaceutical value chains (VC) in Africa could be an effective tool to ensure a stable and long-term expansion. The VC steps can be prioritized in different sequences by identifying the steps which will have the strongest and most immediate impact taking cost, time, and capacity into consideration. Around 100 manufacturers in Africa are limited to packaging where only three manufacturers produce APIs. African manufacturers are highly dependent on imports of APIs mainly from India and China which have implications of the vulnerability of prices and availability throughout the African medical supply chains. Scaling up existing production of APIs in Africa of the generic medicines within MNCH and hypertension will contribute to cheaper medicines and better access across the continent. Other dimensions of the VC can be sequenced to the latter stages of the development of pharmaceutical manufacturing in Africa. This includes the stage of research and development (R&D) which is a highly costly and complex process. At this stage, companies currently make little or no investments in research and development and in protecting intellectual property in Africa. This step in the VC will to a smaller extent solve the immediate challenges of availability of MNCH and hypertension pharmaceutical products but will be important for future capacity and skills of the industry.

6. CONCLUSION

Building a robust pharmaceutical manufacturing industry in Africa by expanding production of essential medical products and technologies for MNCH and hypertension can contribute greatly to Africa's response to current health priorities and develop medical solutions that are more suitable to local contexts.

This report identified a prioritized list of medical products and technologies associated with the two health areas of focus that are considered essential for first-line defense treatment in order to explore the opportunities and challenges behind building a pharmaceutical sector in Africa. The mapping of first-line defense treatment of medical products and technologies for MNCH related diseases identifies eight medicines and four medical devices. The mapping of first-line medical products and technologies for MNCH related diseases for hypertension identified four products for diagnostics and four first-line therapeutic categories. Key challenges identified to the availability of these products include poor quality of medicines and/or the packaging of finished products, the lack of access due to poor cold chain infrastructure, high prices for African buyers compared to global median prices, as well as low awareness and training of personnel in the application of the different pharmaceutical products.

In the market sizing analysis for the MNCH first-line defense medicine oxytocin, it is estimated that Africa today requires 37.38 million doses of oxytocin worth approximately \$6.22 million. This demand is estimated to increase to around 66 million doses valued at close to \$30 million by 2050 driven by higher number of births as well as higher proportion of women giving births at health facilities which unlocks access to essential MNCH medicines. The market size of hypertension care in Africa is estimated to reach \$15.9 billion in annual direct patient costs by 2030 with relatively low awareness and treatment rates of 33.7 and 50 percent, respectively. Provided increased efforts are implemented to diagnose and treat hypertension, the annual direct patient costs could increase almost six times to \$95.38 billion in 2030 with 100 percent awareness and treatment rates. There is evidence, however, that some African countries pay as much as 30 times more for medicines than the indicated global prices. These estimated market values are therefore likely to be at the conservative end of the spectrum.

Africa has one of the fastest growing pharmaceutical industries in the world with a growing market demand that is driven significantly by population growth. Through the lens of first-line defense pharmaceutical products and technologies to diagnose and treat diseases within MNCH and hypertension, there is scope to expand African production of medicines and vaccines based on the grounds of health security and regional supply chain resilience.

With the adoption of the AfCFTA and launch of trade in January 2021, there are areas which the AfCFTA can help remedy in order to boost intra-African trade of pharmaceuticals and strengthen regional supply chains in Africa. The AfCFTA can offer economies of scale for pharmaceutical manufacturers to engage in local production and thereby addressing key obstacles of small fragmented markets and supply chain systems as well as policy incoherencies. Moreover, the analysis shows that many MNCH and hypertensive drugs are available under generic formulations. This supports the objective of building robust pharmaceutical manufacturing capacity in Africa as the technical requirements and production unit economics are lower for generics than for drugs under patent. The ratification of the AMA is an important step to ensure a stable regulatory environment with harmonized rules and regulations of African pharmaceutical manufacturing. This will play a key role to ensure a common set of rules and regulations of manufactured products in Africa to ensure quality of the APIs and the packaging of pharmaceutical products as well to help fight sham and counterfeit products. This further supports access to long term financial support in the sector needed to expand on-the ground production of essential medicines and technologies in Africa.

This report recommends a sequencing strategy to develop value chains of medical products and technologies to diagnose and treat diseases within MNCH and hypertension. The analysis indicates that the low level of local production of APIs on the continent has a high impact on the vulnerability of prices and availability of the African pharmaceutical supply chains. This report therefore recommends African countries to prioritize scaling up existing production of APIs for generic medicines within MNCH and hypertension to facilitate better access to essential medicines at more affordable prices. Other scalable initiatives such as packaging and manufacturing of medical devices can also appear in the first stages of developing the VCs of the manufacturing sector. However, further research should be done to identify and prioritize more VC steps in different sequences by taking impact, cost, time, and capacity into consideration.

Last but not least, given the significant impact that improvements in MNCH and hypertension can have on Africa's health and economies, they are good candidates for inclusion in a burgeoning African generic drug production push. A healthy generic industry can then serve as a platform to develop manufacturing experience and to train the workforce for increasingly more complex products over time.

ENDNOTES

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