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Madison M. Bradley
University of South Carolina - Columbia

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Ironing out anemia: Assessing the role of marketplace factors and government investment incentives in shaping East African pharmaceutical markets

Madison Bradley ^a

^a Department of International Business, University of South Carolina Darla Moore School of Business, 1014 Greene St, Columbia, SC 29208

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ABSTRACT

Africa suffers from the highest disease burden in the world, with over half of the population lacking regular access to essential medicines (Owoeye, 2014, p.214; Chaudhuri & West, 2015, p.23). Following two decades of reform, the continent has now emerged one of the fastest-growing economic regions, shifting public health focus toward non-communicable diseases (NCDs) (Holt et al., 2015, p.2). Among these NCDs is anemia, which has direct and indirect economic effects as large as 4.05% of GDP (Horton & Ross, 2003, p.51). Encouraged by the rapid growth of liberalized markets, African governments and health officials are now considering local pharmaceutical production as a way to unlock the economic, social, and political benefits of improved public health. This thesis explores two hypotheses: (a) tax incentives effectively induce greater foreign direct investment in East Africa, including pharmaceutical production, and (b) local pharmaceutical production in East Africa provides better access to essential medicines like haematinics (anti-anemia drugs) as measured by anemia prevalence in children under five. To facilitate an empirical test of the latter, the former is assumed to be true based on the literature. We study these questions using Ethiopia and Rwanda as representative countries. Taking effect in 2012, Ethiopia's Double Taxation Avoidance Agreement (DTAA) with India created local investment incentives via low rates for dividends, interest, royalties, and fees for technical services as compared to Rwanda, which has no such agreement. We perform a difference-in-differences (DID) regression using data from Demographic and Health Surveys (DHS) to estimate the causal relationship between favorable investment conditions and anemia rates among children. Our results are inconclusive and suggest determinants of anemia are numerous and interconnected.

1. Introduction

Africa is among the world's fastest-growing economic regions with an estimated compound annual growth rate of 9.8% between 2010 and 2020 (Holt et al., 2015, p.2). In 2019, the five fastest growing economies globally were all African (IMF, 2019 as cited in Oguji &

Owusu, 2021, p.5). Over the past twenty years, consumer spending, household income, urbanization, and other income measures have grown dramatically and are expected to continue (Holt et al., 2015, p.2). As these metrics improve, experts predict related booms in the

African drug market, with realistic assumptions as high as 200 percent growth for the next decade (Lucchini, 2018). By 2030, the African pharmaceutical industry is expected to be worth USD \$56-70 billion (“African pharmaceutical,” 2020).

Despite these optimistic numbers, however, “half of the population lack regular access to essential medicines” and 90% of all medicines are imported (Chaudhuri & West, 2015, p.23). According to the World Health Organization (WHO), the proportional contribution of non-communicable diseases (NCDs) to the healthcare burden in Africa will rise by 21% through 2030, driving demand of chronic prescription drugs (“African pharmaceutical,” 2018). Among these NCDs is anemia, “a condition marked by a deficiency of red blood cells for hemoglobin in the blood” (“Anemia,” n.d.). The WHO identifies roughly five anti-anemia medicines as essential (World Health Organization [WHO], 2019, p.33-34).

This thesis studies the impact of locally-produced haematinics versus imports on public health outcomes via marketplace factors. Using Ethiopia and Rwanda as representative countries, we explore the impact of government-imposed investment incentives on the local production market. Taking effect in 2012, Ethiopia’s Double Taxation Avoidance Agreement (DTAA) with India created local investment incentives via low rates for dividends, interest, royalties, and fees for technical services as compared to Rwanda, which has no such agreement.

Ethiopia and Rwanda are appropriate representative countries because they share common age structure, population growth rate, and gross domestic product (GDP) per capita among other factors (Central Intelligence Agency [CIA], 2021a; CIA, 2021d). As we shall see, however, these two countries have sufficiently different political and economic legacies such that they provide a quasi-controlled experiment. Ethiopia acts as the experiment group with its market-oriented 2011 DTAA. Having no DTAA with India, Rwanda, with its economic development strategy of African intracontinental investment, acts as the control. Using a difference-in-differences (DID) regression model with data from Demographic and Health Surveys (DHS), we attempt to estimate the causal relationship between local pharmaceutical production and access to essential drugs like haematinics as measured by anemia prevalence in children under five.

Our DID regression was supplemented by ordinary least-squares (OLS) regressions to confirm the determinants of anemia as presented in the literature. Both OLS and DID regressions were performed at

several levels of outcome specificity and control against endogeneity. Data extraction, recoding, and analysis were performed using STATA version 16 software. Results were reviewed for statistical significance at the 95% confidence interval.

Contrary to our hypothesis, the DID results show a strong positive correlation between the post-DTAA time period and the probability of moderate and severe anemia for Ethiopian children. However, a number of concerns prevent an interpretation of this relationship as causal. Though our data is inconclusive regarding the directionality and magnitude of the effect of local production, our empirical concerns suggest that the determinants of anemia are numerous and interrelated.

2. Literature Review

2.1. Anemia prevalence is negatively related to economic development

Anemia is among the most common medical conditions globally, affecting more than two billion people in the developing world (Schady, 2012, p.887). Characterized by a shortage of oxygen-carrying red blood cells, anemic individuals often experience lethargy, decreased cognition, and lower physical capacity (“Anemia,” n.d.; Horton & Ross, 2003, p.63). A variety of empirical studies show a negative relationship between these biological effects and economic development though productivity, schooling, and mortality.

A 1977 study by Gardner et al. in Sri Lanka found a significant negative correlation between iron deficiency anemia and physical working capacity as measured by heart rate and post-exercise lactate. A 1979 study by Basta et al. in Indonesia found that wages were correlated with hemoglobin levels. After iron treatment, those in the experiment group showed higher work output and decreased morbidity. A similar study in 1994 by Li et al. in China among female mill workers found a significant positive correlation between hemoglobin and productivity efficiency. Iron-treated individuals had higher hemoglobin levels and lower working heart rates than the placebo group, indicating lower energy expenditure. A 2003 study by Horton & Ross across ten developing countries found a causal relationship between iron deficiency anemia and (a) motor and mental impairment in children and (b) low productivity in adults. The median total losses were estimated at 4.05% of GDP based on lost or lowered wages. A 2006 study by Thomas et al. in Indonesia found that anemic individuals treated with iron supplements were better off physically, psycho-socially, and economically than those

that received a placebo. Males in the treatment group enjoyed wages 15% higher than the control. A 2006 study by Bobonis et al. in India found that iron supplementation improved preschool participation rates by 5.8%, suggesting a correlation between anemia and school attendance. These results were supported by a 2012 report by Alcázar in Peru that found economic losses due to anemia amounted to 0.62% of GDP, of which 46.3% was due to cognitive losses, 21.% due to loss and delay of schooling, 18.2% due to lower productivity in adults, and 13% due to delivery care of premature infants. A 2018 study by Ejigu, Wencheke, and Berhane in Ethiopia found a positive correlation between anemia prevalence and poverty and low education - markers of poor economic development.

2.2. Tax incentives effectively induce foreign direct investment

Double taxation avoidance agreements have two objectives: (i) double taxation avoidance, which stimulates FDI and (ii) information sharing to prevent tax evasion, which stifles FDI (Shah & Qayyum, 2015, p.1; Dong, 2019, p.1). Most such agreements, including the 2011 Ethiopian-Indian DTAA, favor the country of residence in tax revenue by offering low rates in the country of source (Neumeyer, 2007, p.1501). Low-income countries rely on the expected FDI inflows to offset the otherwise expensive implementation of DTAAs. Though relevant studies reach mixed conclusions, among these results are evidence that DTAAs are effective in promoting FDI.

Generally speaking, Bora (2002), Blomstrom & Kokko (2003), Easson (2001), and Taylor (2000) find that fiscal incentives are significant determinants and motivators of FDI flows. A 2003 study by Edmiston, Mudd, and Valev found that tax complexity has a negative effect on inward FDI. Therefore, as suggested by Jones (1996) and Gravelle (1988), DTAAs should encourage FDI just by providing tax stability.

A 2010 study by Botman et al. in East Asia found that reduced corporate income tax rates and low taxes on gross receipts (which include dividend and interest income) would attract inward FDI. These conditions are similar to those offered by most DTAAs. Similarly, a 2010 study by Barthel et al. across both developed and developing countries found that DTAAs increased FDI by between 27 and 31%. A 2019 study by Dong across ten southeast Asian countries found a positive (though insignificant) correlation between FDI inflows and DTAAs.

2.3. Local production provides better access to essential medicines than imports

Given the proper conditions, such as economies of scale, a cohesive regulatory environment, and necessary infrastructure, among others, local pharmaceutical production is found to provide better access to essential medicines via lower costs and easier distribution (Mohamed, 2018, p.26; Conway et al., 2019, p.6).

Kuanpoth (2007) and Chowdury & Kabir (2009) in Vietnam and Bangladesh, respectively, found that locally-produced medicines were considerably less expensive than their imported counterparts. A 2020 study by Boateng et al. in Ghana found that a lack of locally-produced essential cancer drugs both limits availability and inflates price.

Contingent on sufficient market access, a 2014 simulation study by Chaudhuri & West in Ghana found that local producers could manufacture essential drugs at prices competitive with Indian exporters. Likewise, a 2019 study by McKinsey & Company researchers Conway et al. found that if scale and utilization are held constant, local production can lower prices as compared to imports. Studies by Mujinja et al. (2014) and Chaudhuri et al. (2010) in Tanzania found that local production improves rural and low-income access to medicines as compared to imports, especially those from India. A 2017 study by Ewen et al. in Ethiopia found that local production was associated with 29% and 19% better availability in the public and private sectors, respectively, as compared to imports. Patients paid 53% more than the government procurement price for imported medicines as compared to 17% more for those locally-produced.

3. Background

Global pharmaceutical production is highly concentrated, leaving most developing countries with either no industry at all or only relatively late-stage manufacturing (Chaudhuri & West, 2015, p.23). African countries have historically been treated as a market for exports rather than production sites for foreign manufacturers (Chaudhuri & West, 2015, p.23). In recent years, however, many African countries have attempted to spur local production to improve access by lowering costs.

Simplistically speaking, pharmaceuticals may be either (a) branded or generic and (b) imported or locally-produced. These four combinations differ in investment model, manufacturing requirements, resulting price to payer, and ultimately consumer access (Chaudhuri & West, 2015, p.24; Conway et al., 2019, p.5). In Africa, a

growing market for generic drugs has supported government initiatives to attract foreign direct investment.

Though largely driven by epidemiological needs, markets are sensitive to the policies of international health organizations, domestic governments, corporate producers, and local doctors. Of particular importance is the “patent cliff,” or the date at which a branded pharmaceutical’s patent expires, thereby allowing generic manufacture to begin (Miglierini, 2019; “Patent cliff,” 2018). Generics generally represent cheaper alternatives to branded drugs when both are produced domestically, but in many developing countries, branded manufacture takes place abroad and therefore requires importation. The costs of imports, driven specifically by high logistics costs and taxes, mean that purchasing abroad may increase the price of drugs for final sale beyond the reach of all those who need it (Conway et al., 2019). However, the alternative – local production – also faces structural barriers including lack of infrastructure, access to qualified personnel, and power interruptions, among others which could impede access (Mohamed, 2018, p.16).

The benefits of local production over imports are debated and largely country-specific. Nowhere is this question of greater relevance than in sub-Saharan Africa, where as of 2019, as much as 70 to 90 percent of drugs were imported and over half of the population lacked access to essential medicines (Kaine & Nwokike, 2020; Chaudhuri & West, 2015, p.23). Among these essential medicines are haematinics, drugs used to treat anemia.

3.1. Anemia

Anemia is a medical condition marked by a deficiency of red blood cells, which contain the oxygen-carrying protein hemoglobin (“Anemia,” n.d.). Of the estimated two billion cases of anemia in the developing world, half are attributed to iron deficiency (FAO/WHO, 19992; WHO, 2009 as cited in Schady, 2012, p.887). Iron deficiency without anemia is believed to be equally widespread (Horton & Ross, 2003, p.52).

Iron deficiency is the most common nutritional deficiency globally (Horton & Ross, 2003, p.52). Iron is necessary for the production of red blood cells, and deficiency therefore often leads to anemia (Horton & Ross, 2003, p.52). Prevalence rates are especially high among pregnant women and young children, especially given the continued prevalence of maternal undernutrition (Schady, 2012, p.887; Monterrosa et al., 2018, p.1). A 2018 study by Ejugi, Wencheke, and Berhane found that “anemia prevalence decreases as

wealth index and educational level increase for both genders” (p.5).

According to professor and World Bank advisor Norbert Schady, “traditionally, efforts to combat anemia in developing countries have focused on fortification or iron supplementation... [or the] provision of dietary supplements” (2012, p.887). As a complement, this thesis explores the impact of marketplace factors on access to the haematinic drugs listed under section 10.1 of the WHO’s 21st Model List of Essential Medicines (World Health Organization [WHO], 2019, p.33-34). The list includes four core medicines; ferrous salt, ferrous salt + folic acid, folic acid, and hydroxocobalamin; and a complementary list of erythropoiesis-stimulating agents (WHO, 2019, p.33-34).

Anemia represents a particular concern among developing countries because of its impact on productivity. Common symptoms of iron deficiency anemia (IDA) include tiredness and lethargy due to the role of hemoglobin in transporting oxygen to the muscles, brain, and other tissues (Horton & Ross, 2003, p.63). Anemic individuals therefore demonstrate limited physical and cognitive performance compared to their healthy counterparts (Horton & Ross, 2003, p.63).

Anemia during pregnancy increases risk of preterm delivery, low birthweight, and infant mortality (Monterrosa et al., 2018, p.1). Anemic mothers are also more likely to have anemic children, creating an intergenerational cycle of malnutrition (Monterrosa et al., 2018, p.1). Observational studies of the relationship between IDA and mental capacity find that infants with moderate IDA score 0.5 to 1.5 standard deviations below those with sufficient iron on the Bayley scale of development (Horton & Ross, 2003, p.53). Long-term studies in the United States and Indonesia also found impacts on motor development (Aukett et al., 1986; Idjradinata & Pollitt, 1993 as cited in Horton & Ross, 2003, p.54). These developmental delays are found to be at least partially reversible with iron therapy (Horton & Ross, 2003, p.58).

If uncorrected, however, cognitive losses of iron deficiency are costly. A study in Colombia found that a one standard deviation improvement in cognitive scores produced a 7-9% increase in hourly earnings (Psacharopoulos & Velez, 1992 as cited in Horton & Ross, 2003, p.51). Similar studies in Kenya and Tanzania found improvements of 17-23% and 8-13%, respectively (Horton & Ross, 2003, p.51). Because healthy children are more likely to remain in school, the benefits of improved cognitive development as a result of anemia treatment are compounded by indirect effects of greater education (Horton & Ross, 2003, p.61).

In terms of physical productivity, improvements of 17% and 5% were observed among anemic rubber workers in Indonesia and cotton mill workers in China, respectively (Basta et al., 1979, p.916; Li et al., 1994, p.908). A 2006 study by Thomas et al. in Indonesia found that anemic males given iron supplements earned 15% higher wages than those who received a placebo (p.22). A 2003 study by Aguayo, Scott, and Ross in Sierra Leone found that agricultural productivity losses caused by anemia in women generated losses of \$19 million annually (as cited in Caulfield et al., 2006).

The combined loss from physical and cognitive underdevelopment due to IDA is estimated at 4.05% of GDP (Horton & Ross, 2003, p.51). This estimate is even greater if one considers the economic and social costs of the 20% of maternal deaths in Africa attributable to IDA (Horton & Ross, 2003, p.71). Though these valuations are reliant on a handful of well-controlled studies, scholars generally agree that anemia represents a large and growing public health concern (Horton & Ross, 2003, p.72).

Figure A1 from the Institute of Health Metrics and Evaluation (IHME) shows iron deficiency as the leading risk for years lived with disability in 2015 for children under five in Ethiopia, Rwanda, sub-Saharan Africa, and Brazil, Russia, India, and China, collectively referred to as BRIC, to which Africa is often compared (2019). Child underweight, wasting, and low birth weight also rank within the top eight, and are correlated with anemia (Yang et al., 2012, p.1; Monterrosa et al., 2018, p.1). The United States is added as a comparison. *Figures A2* and *A3* show that mild and moderate anemia are the leading impairments in Ethiopia, Rwanda, and sub-Saharan Africa in 2015 both for children under five and across age groups (IHME, 2019). Impairments are those health concerns for which there are several underlying causes (IHME, 2018). Anemia also ranks within the top ten for the BRIC countries, and the United States is again included for reference (IHME, 2019). As of 2016, the World Bank estimates that as many as 50% of Ethiopian and 36.2% of Rwandan children under five are anemic (World Bank, 2016). Our selection of anemia prevalence as our health measure of interest is justified by the similar health development status of our comparison countries Ethiopia and Rwanda and is motivated by the relevance of anemia to the developing world at large.

3.2. African pharmaceutical market

The African drug market is growing rapidly in response to political and economic changes over the past twenty years. Between 2017 and 2030, prescription drugs generally are forecasted to grow at a compound

annual growth rate (CAGR) of 6.5%, while generics specifically are expected to grow at 10% (“African pharmaceutical,” 2020). With 15% of the global population and 24% of its disease burden, the region presents ample opportunity for “multinational corporations (MNCs) and local pharmaceutical companies seeking new sources of growth” (Ford, 2017, p.40; Holt et al., 2015, p.2).

With a 1930 investment in Kenya, MNCs became the first to set up pharmaceutical manufacturing facilities in sub-Saharan Africa (Lartey et al., 2018, p.1). In the 1960s, indigenous companies appeared and set a period of exponential growth into motion (Lartey et al., 2018, p.1). Since the 1970s, the African pharmaceutical sector has enjoyed substantial growth and now includes over 300 facilities (Lartey et al., 2018, p.1).

The development of the Indian market followed a similar timeline. Manufacturing began in 1930, and in response to extensive planning and government funding, hit a period of exponential growth in the 1970s (Lartey et al., 2018, p.3). The Indian pharmaceutical industry currently ranks third globally in terms of volume (Lartey et al., 2018, p.3).

Unlike India, the African market is highly concentrated - 80% of manufacturers are located in just eight countries, which limits domestic self-sufficiency (Kaufman et al., 2021). Even the most generous estimates only show 30% of sub-Saharan Africa’s medicine needs as met by local industry (Lartey et al., 2018, p.1). Instead, African drug demand is met by a combination of foreign aid donations and imports from Indian generics manufacturers and Chinese suppliers (Lartey et al., 2018, p.5; Ford, 2017, p.40). This import reliance results in shortages during health emergencies and limits access to essential medicines, ultimately resulting in adverse public health outcomes (Lartey et al., 2018, p.2; Chaudhuri & West, 2015, p.23). In 2011, “61.2% of deaths in the WHO Africa Region...were caused by communicable diseases, maternal and neonatal diseases, and nutritional deficiencies that in many instances can be treated successfully with pharmaceutical agents” (Owoeye, 2014, p.214).

Besides potentially improving access to essential medicines, local drug manufacturing contributes to poverty reduction by providing high-quality, technology-based jobs throughout the supply chain (Holt et al., 2015, p.2; Lartey et al., 2018, p.2). Though the African Development Bank boasts that “Africa’s pharmaceutical industry is the fastest growing in the world,” the 2019 valuation of the sub-Saharan market at \$14 billion is quite small in comparison to India (\$19 billion) and China (\$120 billion) (Ford, 2017, p.41;

Conway et al., 2019, p.3). Foreign firms often shy away from the comparatively challenging business environment of Africa, citing high transaction costs, institutional distance and uncertainty, and a “high liability of foreignness” (Gundelach & Hansen, 2020, p.175; Wrona & Trapeczynski, 2012, p.298; Kostova, 1999; Kostova & Zaheer, 1999 as cited in Gundelach & Hansen, 2020, p.175). In response, many governments have developed initiatives to plan for and incentivize foreign investment.

Since the 1990s, liberalization and regulatory reform has drawn the attention of European and Asian MNCs seeking first-mover advantages (Wrona & Trapeczynski, 2012, p.298; Gundelach & Hansen, 2020, p.175). The African pharmaceutical industry is projected to be worth over \$40 billion by the next decade, due to a combination of four factors: (a) population growth (b) maturing of the business environment (c) rise of major cities and (d) improved healthcare capacity (Lartey et al., 2018, p.1; “African pharmaceutical,” 2020).

3.2.1. Population growth

Sub-Saharan Africa is expected to double its population by 2050 to 2.5 billion, representing more than one quarter of the world’s people (“Africa’s population,” 2020). Life expectancy is also rising (“Ford, 2017, p.40). These changes will produce more potential customers for pharmaceuticals. Estimations of Africa’s population growth are considered reliable because of “population momentum,” meaning that the sheer number of women of childbearing age mitigates the effects of even conscious efforts to lower fertility rates (“Africa’s population,” 2020). Africa’s population growth of 2.7% annually exceeds that of other developing regions including South Asia (1.2%) and Latin America (0.95%) (“Africa’s population,” 2020).

3.2.2. Maturing of the business environment

Following the socio-economic crises of the 1980s and early 1990s, African governments began comprehensive and systematic macroeconomic reform to liberalize markets (Anyanwu, 2006, p.43). As the newly sanctioned capitalist markets grew more productive in allocating wealth, state investors began to target the region as both source and export markets (Anyanwu, 2006, p.43; Vickers, 2013, p.675). Among these investors are firms headquartered in BRIC countries (Vickers, 2013, p.675). “Mindful of the effect of drug imports on the balance of trade,” many governments offer tax exemptions and other benefits to incentivize local manufacturing (Holt et al., 2015, p.5; Sadana et al., 2018, p.21). Increased market activity has

contributed to improvements in GDP, consumer spending, and household income.

3.2.3. Rise of major cities

37% of African consumers are concentrated in just 30 cities; experts predict these cities alone will have more consuming households by 2025 than Australia and the Netherlands combined (“African pharmaceutical,” 2020). This is critical to pharmaceutical demand because “cities enjoy better infrastructure and healthcare provision than rural areas, and urban middle-class households have more purchasing power and are quicker to adopt modern medicines” (Holt et al., 2015, p.5; Mohamed, 2018, p.15).

3.2.4. Improved healthcare capacity

Between 2005 and 2012, African healthcare capacity grew by 70,000 hospital beds, 16,000 doctors, and 60,000 nurses (Lucchini, 2018). The shifting burden of disease to NCDs drives the demand for chronic prescription drugs, which are becoming more easily available through pharmacy chains backed by private-equity investors (“African pharmaceutical,” 2018; Holt et al., 2015, p.5). New public and private insurance programs help increase access and affordability of these new medications (Sadana et al., 2018, p.21).

Africa’s pharmaceutical market and economic development are linked: as individuals become wealthier, they seek better and more frequent access to healthcare. However, besides the wealthy, even poor individuals need access to medication. Despite rapid improvements to capitalist markets and growing consumer power, Africa remains the world’s poorest region and home to more than half of the world’s extreme poor (Vickers, 2013, p.67; “The number,” 2018). The question of whether local production or imports meets these pressing needs better is a focus of this study.

3.3. Generic drug market

A generic drug is a medication produced to have the same dosage, safety, strength, route of administration, quality, and performance characteristics as an existing brand-name drug (“Generic drug facts,” 2018). Generics are produced after the expiration of the branded drug’s patent (National Association of Pharmaceutical Manufacturers [NAPM], 2009, p.138). Because the producers bear the cost of neither research and development nor extensive marketing, generic drugs are typically less expensive. For these reasons among others, generic drugs are gaining market share at the expense of branded medications in many African

countries (Holt et al., 2015, p.6). Generic anti-anemia medicines are comprised of generally simple, small molecules. Production of drugs of this nature is fairly straightforward because the economic and “technical challenges would vary for more complex products, such as combination drugs, injectables, and vaccines” (Conway et al., 2019, p.1).

The rise in popularity of generics is due to four key shifts: (a) recommendation by medical professionals (b) expansion of insurance programs (c) government support and (d) compulsory licensing.

3.3.1. Recommendation by medical professionals

Medical professionals increasingly prescribe generic drugs and recognize them as useful alternatives (Holt et al., 2015, p.6). This is partially due to the rising incidence of chronic lifestyle diseases, which generates greater demand for prescriptions (Lucchini, 2018). South Africa, for example, requires pharmacists to inform private patients about generic alternatives (Holt et al., 2015, p.6). It is important to note, however, that in some cases negative perceptions of local products (which are usually generics) result in customers paying “more for international branded generics as a proxy for quality” (Mohamed, 2018, p.16; Kaufman et al., 2021).

3.3.2. Expansion of insurance programs

As national insurance programs expand due to economic and political development, more individuals are covered. Public-private partnerships are also expanding as healthcare markets liberalize (Sadana et al., 2018, p.21). As low-cost alternatives to branded drugs, generics are popular among insurers (Holt et al., 2015, p.6).

3.3.3. Government support

Governments support generics and domestic manufacturing capacity because of the economic, political, and health benefits of industry growth (Holt et al., 2015, p.6). According to the National Association of Pharmaceutical Manufacturers, “because generics lower total funder expenses, the use of generics makes funds available to be used for new innovative drugs from originator companies,” thereby providing governments the budgetary flexibility necessary to support drug access for more citizens (2009, p.144). Government subsidy is especially important in developing countries, as pharmaceuticals are often the largest household health expenditure and a major cause of household impoverishment (WHO, n.d.) Since 2013, the African generic market has grown by 9% annually (Lartey et al., 2018, p.1).

3.3.4. Compulsory licensing

In 1994, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement required signatories to recognize patents for all eligible pharmaceutical products (Owoeye, 2014, p.214). However, in response to public health needs, the Doha Declaration was signed in 2001 to grant “member states of the World Trade Organization the right to adopt legislation permitting the use of patented material without authorization by the patent holder, a provision known as ‘compulsory licensing’” (Owoeye, 2014, p.214). Because most African countries are on the World Trade Organization’s list of low-income countries, this exempts them from complying with patents for pharmaceuticals until 2033 (United States Agency for International Development [USAID], 2016, p.1). African countries are therefore incentivized to develop local manufacturing capacity now to enjoy the benefits of compulsory licensing while international intellectual property law is flexible (Owoeye, 2014, p.214). Rwanda is an exception in that it has fully aligned its intellectual property law with that of TRIPS and other international conventions to which it is a signatory (Owoeye, 2014, p.215). This may improve communication with international suppliers (see: 6.2.2.3 *Intellectual property law*).

Despite these growth factors, at present, local manufacturing capacity in Africa remains underdeveloped. Most countries are still reliant on imports to meet public health needs, as foreign manufacturers prefer an arms-length approach to market entry given (real or perceived) barriers to entry (Owoeye, 2014, p.214; Chaudhuri & West, 2014, p.23). Even the incentives of compulsory licensing have been insufficient to spur significant capacity building (Owoeye, 2014, p.215). In fact, pharmaceutical MNCs have raised few concerns over TRIPS compliance because the dearth of infrastructure in Africa makes large scale compulsory licensing unlikely (Owoeye, 2014, p.215). As such, recent studies show that only about 40% of public sector and 60% of private sector pharmaceutical outlets offer generics (Owoeye, 2014, p.214). In the private sector, generics are on offer at 6.7 times the international reference prices – low as compared to originator brand medicines, which can be as much as 20.5 times the reference prices (Owoeye, 2014, p.214).

Although African countries can import generics, current issues with TRIPS compliance in India may soon reduce the availability of these drugs for export (Owoeye, 2014, p.214-215). According to professor Olasupo Owoeye, “as emerging economies in Asia begin to implement a more protectionist intellectual property

framework, Africa is ill-advised to continue relying on generic manufacturers in Asia for access to affordable pharmaceuticals” (2014, p.217). Combined with the increasing tendency for MNCs to produce their own generics and price erosion across the industry, the need for African manufacturing capacity is urgent (NAPM, 2009, p.143-144; Owoeye, 2014, p.217). Local production also reduces foreign dependence, which improves public health by making supplies more reliable (Chaudhuri & West, 2014, p.24; USAID, 2016, p.1).

Though local production offers many advantages, MNCs are quick to point out its many challenges. Africa suffers from cost disadvantages including lack of skilled labor, high cost of inputs, lack of infrastructure, and high cost of financing (Chaudhuri & West, 2014, p.24). As Chaudhuri and West explain, “it is a widely held view in health policy circles that if African countries with higher costs try to promote local production then prices will be higher than that of imported medicines and hence, local production will negatively impact access” (2014, p.24). Conversely, advocates of local production argue that a lower profit margin can be offset by a larger volume of sales (Chaudhuri & West, 2014, p.24). In rural areas, locally-produced medicines are used more often than their imported equivalents, suggesting a direct correlation between local capacity and access (Lartey et al., 2018, p.2).

3.3.4.1. Implications for investment

Not only may compulsory licensing improve access to essential medicines, but such local production may even be profitable. Traditionally, “foreign manufacturers located in countries such as India have treated [African] countries essentially as a market for their exports rather than taking the initiative to produce there” (Chaudhuri & West, 2015, p.23). An estimated 70 to 90% of sub-Saharan Africa’s pharmaceutical needs are currently met through imports – far exceeding the foreign dependence of other developing regions such as India and China who import just 5 and 20%, respectively (Conway et al., 2019, p.1). Local African producers hold just 20% of the pharmaceutical market primarily due to capacity constraints, but also because aid organizations tend to purchase from Western firms or India (Ford, 2017, p.40). Foreign MNCs enjoy better reputations and thus “dominate the market despite charging higher prices” (Chaudhuri & West, 2015, p.34). Though many foreign exporters, unlike African manufacturers, are GMP-compliant, locally-produced drugs are generally safe and effective (“LABOPHAR eyes,” 2010).

Though currently drugs are cheaper when imported, some studies suggest that “with comparable facilities

some drugs tomorrow could be cost competitive or even cheaper than imports from India,” especially in the case of generics or basic oral solids such as haematinics (Conway et al., 2019, p.5). A 2019 study by McKinsey & Company in Ethiopia, for example, found that an imported drug’s landed price includes the Indian manufacturer’s price “plus a more than 20% markup as a result of freight, duties, and value-added tax” (p.5). If that same drug were produced in Ethiopia, “the raw materials would still be imported, but the import costs would be lower because of their relatively low value” (Conway et al., 2019, p.5). Adding in additional costs of lower manufacturing efficiency and producer margins, the total cost at the end of manufacturing is higher than in India (Conway et al., 2019, p.5). However, domestic production reduces logistics costs for distributors, so at the point of entry into the local supply chain, the Ethiopian-manufactured drug is 5 to 15% more affordable for the end user (Conway et al., 2019, p.5). This scenario is illustrated by *Figure A4*. It is important to note, however, that this situation is largely theoretical due to low current capacity and utilization rates in Africa (Conway et al., 2019, p.6).

3.4. Hypotheses

Based on our background research, our hypotheses are (a) tax incentives effectively induce greater foreign direct investment in East Africa, including pharmaceutical production, and (b) local pharmaceutical production provides better access to essential drugs like haematinics as measured by anemia prevalence in children under five. To facilitate the empirical testing of the latter, the former is assumed to be true based on the literature.

Hypotheses

- (a) Tax incentives effectively induce greater foreign direct investment in East Africa, including pharmaceutical production*
- (b) Local pharmaceutical production in East Africa provides better access to essential drugs like haematinics as measured by anemia prevalence in children under five.*

3.5. Ethiopia, Rwanda, and India

Ethiopia is the fastest growing economy in sub-Saharan Africa and the second largest population (World Bank, 2021). Likewise, Rwanda is also rapidly growing due to political and economic reforms over the past two decades (CIA, 2021d). Both countries act as major trading partners for India, enjoying both FDI and imports in the pharmaceutical sector.

3.5.1. Country comparison empirical justification

DID regressions require the parallel trends assumption, wherein changes in the treatment group over time are expected to be the same as the control group if no treatment were administered. Similarities between Ethiopia and Rwanda support this assumption as much as possible given the limitations of the experimental design (see: 4. Empirical Methodology).

In the mid-1990s, Ethiopia and Rwanda appeared poorly positioned for economic development (Reynolds, 2018). Having just emerged from violent civil wars, both countries ranked among the world's poorest with GDP per capita of less than \$150 (Reynolds, 2018). Yet as economist Oliver Reynolds explains, "fast forward just 25 years and...they are arguably the two most economically dynamic countries in the whole of Africa" (2018). With annual growth rates of 10% and 7% in Ethiopia and Rwanda respectively over the past decade, their success is touted as proof of Africa's ability to punch above its weight (Reynolds, 2018).

In both countries, economic development started at the top with the long-term policies of technocratic leaders (Reynolds, 2018). The idea was to move up the value chain – kickstarting a positive feedback loop of capital accumulation (Reynolds, 2018). Industrialization from an agrarian economy to manufacturing and services would create jobs for the rapidly-growing and urbanizing middle class. With higher incomes, those individuals would then engage in the local and international economy as consumers.

Despite differences in size – Ethiopia's 110 million citizens are more than eight times Rwanda's 12.9 million – the countries' population structures are remarkably similar (CIA, 2021a, CIA, 2021d). With over 39% of each population under 14 years of age and a median age of just 19, Ethiopia and Rwanda are rich in young talent. Plus, this pool is only growing – both countries have population growth rates of roughly 2%, with about one-fifth concentrated in urban areas (CIA, 2021a; CIA, 2021d). Urbanization rates are also high at 4.63% in Ethiopia and 2.86% in Rwanda (CIA, 2021a; CIA, 2021d). Combined with rising life expectancies and falling infant mortality rates, the Ethiopian and Rwandan

workforce is expanding, creating new opportunities for labor intensive industries like manufacturing (World Bank, 2016).

Economically, the countries have enjoyed similar improvements to wealth at the household level since the mid-1990s, with real GDP per capita now estimated at just over \$2,220 (CIA, 2021a; CIA, 2021d). It is important to note, however, that Ethiopia's large population results in significantly larger total GDP. In both countries, industry (which includes pharmaceutical manufacturing) now accounts for roughly one-fifth of GDP (CIA, 2021a; CIA, 2021d). A full comparison is available in *Table 1*.

3.5.2. Ethiopia

Ethiopia's development has focused primarily on manufacturing, which it hopes will represent 20% of GDP by 2025 (Reynolds, 2018). The government's industrializing strategy is designed to provide international access to the domestic market, and thus includes agreements with key state investors and trade partners, such as India. This approach attempts to capitalize on the opportunities presented by Ethiopia's changing demographic and health conditions, while building local capacity to address related challenges.

3.5.2.1. Development status

Although Ethiopia has enjoyed an average annual growth rate of 14% over the last ten years, making it one of the fastest-growing economies globally, the country remains quite poor (ITA, 2020a). Over 70% of Ethiopians are employed in the agricultural sector, more than 80% live in rural areas, and as of 2014, nearly 30% of lived below the poverty line (CIA, 2021a). Ethiopia also suffers from a high burden of disease, especially major infectious diseases like malaria, though this is gradually shifting to NCDs (CIA, 2021a).

Over the past twenty years, Ethiopia has slowly begun privatizing state-owned enterprises, making a significant liberalizing shift from a planned economy towards "market-based reforms and new flexibility" (ITA, 2020a). Government efforts to attract FDI from China, Turkey, India, and the EU have resulted in improvements to infrastructure, enabling growth in the industry and service sectors (CIA, 2021a). In fact, industry and manufacturing's share of GDP, driven primarily by construction, rose consistently from 2005 to reach 28.1% in the 2018/2019 Ethiopian fiscal year (ITA, 2020a). As of 2017, the industrial production growth rate was an optimistic 10.5%, suggesting continued improvement (CIA, 2021a). This industrial development is particularly important given Ethiopia's growing and increasingly wealthy middle class (ITA,

Table 1. Ethiopia and Rwanda comparison.

Development markers and their values		
Geography	Ethiopia	Rwanda
Location	East Africa; borders Djibouti, Kenya, Somalia, South Sudan, Sudan	Central East Africa; borders Uganda, Tanzania, Burundi, and the DRC
Size	Just less than twice Texas	Smaller than Maryland
Landlocked	Yes	Yes
Economic development		
Population	110 million	12.9 million
Growth rate	2.5%	1.8%
Urban concentration	17.4%	21.7%
Urbanization rate	4.63%	2.86%
Living in rural areas	80%	82.7% ¹
Employed in agriculture	70%	75.3%
Below poverty line	30%	39%
Real GDP PPP	\$248.9 billion	\$28.1 billion
Real GDP per capita	\$2,221	\$2,227
Industry percentage of GDP	21.6%	17.6%
Import status	\$15.59 billion; 6.4% from India	\$1.922 billion; 7% from India
Annual growth rate, last decade	14%	7%
Primary development strategy	Privatization and market-based reform; focus on manufacturing ^{2, 3}	Transition into regional trade, logistics, conference hub; focus on manufacturing and services ^{2, 4}
Ease of Doing Business Ranking	159th	38th
DTAA with India	Yes ⁵	No
Health development		
Age structure	70% of population under 30; median age 19	60% of population under 24; median age 19
Anemia prevalence, children under 5	50% ⁶	36% ⁶
Burden of disease	Significant; shifting to NCDs but continued significance of infectious diseases	Significant; shifting to NCDs but continued significance of infectious diseases
Health expenditure percentage of GDP	3.3%	7.5%
Trust in institutions		
Institutions global ranking (1 best)	126th ⁷	36th ⁷
Public services score (1 best), considers access to medicine	8.8 ⁸	7.4 ⁸
Prevalence of bribery among healthcare and medical services	35% ⁹	1% ⁹

Notes: Information reflects the most recent data available from the CIA World Factbook (CIA, 2021a; CIA, 2021d) unless otherwise noted.

¹World Bank, 2019b. ²Reynolds, 2018. ³ITA, 2020a. ⁴ITA, 2020b. ⁵DTAA, 2011. ⁶World Bank, 2016. ⁷World Bank, 2019a. ⁸World Bank, 2017. ⁹World Bank, 2013.

2020a; Mubila & Aissa, 2011 as cited in Addae & Addae, 2013, p.29).

Despite these changes, however, the 2020 World Bank's Ease of Doing Business report ranked Ethiopia an unenviable 159th out of 190 countries (ITA, 2020a). According to the World Economic Forum, "burdensome customs administrative procedures, the high cost of logistics, and access to credit and foreign exchange" remain major challenges for small- and medium-enterprises (ITA, 2020a).

3.5.2.2. Pharmaceutical industry

Ethiopian industrial policy views local production of essential medicines as a strategic priority (Bate, 2008 as cited in Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.78). Local production began in 1964 with the founding of EPHARM, a joint venture between the Ethiopian government and British company Smith & Nephew (see: *Case Study B1*) (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.66). Following the establishment of the democratic government, local manufacturing experienced rapid growth between 1995 and 2004 (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.67). The new government, however, had not yet implemented policies or regulatory mechanisms "to control dumping of cheaper and substandard products," so "the prices of local products were not competitive" (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.67). Four of the ten new companies subsequently "foreclosed for failure to service their loan obligations" (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.67).

In 2005, GOE implemented a variety of policy reforms to correct for institutional failures (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.68). Improvements to the business environment resulted in new joint ventures, including Cadila Pharmaceuticals (see: *Case Study B3*) (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.68).

As of 2016, the Ethiopian pharmaceutical industry consisted of 15 manufacturers, all of which have relatively low production capacity, relying on "labor-intensive, step-by-step manual manufacturing, with semi-automated production lines" (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.69). The Ethiopian industry is limited to secondary manufacturing combining imported APIs and excipients into final dosage forms (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.65-70). *Appendix B* provides a detailed review of foreign investment strategies.

"Although the Ethiopian pharmaceutical market grew on average 20% per annum from 2007 to 2011," it is valued at just \$600M primarily because of low per

capita income (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.72; Conway et al., 2019, p.7). The country is heavily reliant on imports across the economy: over the past ten years, imports have increased 12.5% annually, resulting in a 316% increase in value from 2010 to 2018/2019 and creating significant current account deficits (International Trade Administration [ITA], 2020; CIA, 2021a).

Advocates estimate that an increase in local share of production from 15 to 40% would improve trade balances by \$150 to \$200 million annually (Conway et al., 2019, p.1). According to the International Trade Association, such improvements are quite possible, as "factors of production in Ethiopia such as land, labor, and energy costs are low relative to African and other global markets" (2020). Furthermore, industrialization plans include expanding power generation capacity and increased FDI due to tax incentives (CIA, 2021a). Critics, however, dismiss local production over quality concerns (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.78). *Table 2* summarizes Ethiopia and Rwanda's pharmaceutical capacities using criteria established in a 2018 report by Nazeem Mohamed, Chairman of the Federation of East African Pharmaceutical Manufacturers Association. *Appendix C* expands on *Table 2*.

3.5.2.3. DTAA

In 2011, Ethiopia signed a double taxation avoidance agreement (DTAA) with India. By streamlining tax procedures and introducing low, stable rates, the agreement was celebrated as fostering economic cooperation and FDI, especially in high-value sectors like technology and services ("India and Ethiopia," 2011; DTAA, 2011). Though signed in 2011, the agreement came into effect October 2012 in Ethiopia and April 2013 in India (DTAA, 2011).

The agreement sets maximum income tax rates at 7.5% for dividends and 10% for interest, royalties, and fees for technical services in the country of source (ASEAN Briefing, 2011). An enterprise's "country of source" is the one in which it earns profits through a permanent establishment situated therein (DTAA, 2011). Examples of permanent establishments include branches, factories, and subsidiaries ("India and Ethiopia," 2011).

Dividends, interest, royalties, and fees for technical services may be taxed in both the country of residence and the country of source, but when the beneficial owner of such income is a resident of the country of residence, the tax caps in the country of source are 7.5% (dividends) and 10% (interest, royalties, and fees for technical

Table 2. Ethiopia and Rwanda pharmaceutical production capacity.

Pharmaceutical capacity factors and their description		
Current status	Ethiopia	Rwanda
Local manufacturing	Yes; secondary manufacturing of final dosage forms ¹	No; zero production since 2013 ²
Import Reliance	Local production holds roughly 15% market share, for which 95% of APIs and raw packaging materials are imported ^{3, 1}	Fully-import reliant; most imports made via state-owned procurement agencies ⁴
Capacity factors		
Economies of scale	Open tender procurement system does not favor local production; other local production incentives (i.e. tax breaks, customs exemptions) are positive signs of government support ^{5, 6}	Streamlining of business registration to one day encourages FDI; incentives available for investment in special economic zones ^{16, 17}
Potential market	Membership in COMESA offers preferential tariffs among 19 member countries; potential trading partners with the Middle East due to proximity ⁷	Membership in East African Community (EAC) used as a constraint; demonstrated preference for EAC in import duties, hiring, visas ¹⁸
Regulatory environment	Fragmented and highly complex resulting in MNC preference for local partners, but large regulatory budget and efforts at reform ^{8, 3}	Complex and inefficient; inconsistent application of incentives ^{18, 19}
Input materials	Almost all inputs imported including machinery and technical assistance; foreign reliance results in higher logistics, insurance, inventory, and interest costs ^{7, 1, 9}	Government payments often delayed; reliant on imports for APIs, excipients, and machinery (pre-2013) ^{18, 19}
Capital investment, financing	Acute foreign exchange shortage delays procurement and results in exposure to price fluctuations; high inflation; difficult loan approval; reliance on foreign aid ^{10, 1, 11, 12, 13}	High interest rates; limited capital markets ¹⁸
Skilled personnel	Low wages attractive to investors, but largely offset by low productivity due to limited technical skills ^{14, 9}	Shortage of skilled labor ¹⁸
Infrastructure	Limited transportation infrastructure creates long lead times and higher communication, inventory, and insurance costs; low capacity utilization increases cost per unit ^{15, 1}	Limited transportation infrastructure; exceptionally high electricity costs ^{18, 19}
Access to technology	Introduction of new logistics management systems improved inventory management; general lack of reliable data ^{10, 8}	General lack of reliable data ⁸

Notes: ¹Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.65-83. ²Hazikimana, 2021. ³Conway et al., 2019, p.1, 7. ⁴Uwizeyimana et al., 2021, p.3. ⁵ITA, 2020a. ⁶"Local pharma," n.d. ⁷EFDRE, 2015, p.3-4. ⁸Lartey et al., 2018, p.5-6. ⁹Chaudhuri & West, 2015, p.31-32. ¹⁰ITA, 2020a. ¹¹Pletcher, 2020. ¹²Hailu, 2017, p.37. ¹³Owoeye, 2014, p.215. ¹⁴Gebre, 2018. ¹⁵Holt et al., 2015, p.9. ¹⁶USDOC, 2018. ¹⁷Steenbergen & Javorcik, 2017, p.2. ¹⁸ITA, 2020b. ¹⁹USAID, 2016, p.1-3.

services) (DTAA, 2011). This streamlines tax reporting and prevents excess tax costs for MNCs. It also necessitates the sharing of information including banking data, domestic legislation changes, and investment proposals (DTAA, 2011; ASEAN Briefing, 2011). Double taxation is avoided by allowing

individuals to, on the tax documents of their country of residence, deduct an amount equal to the tax paid in the income's country of source (DTAA, 2011).

The provisions for fees for technical services are of particular importance for Ethiopia, given the government's focus on development via manufacturing.

The DTAA describes fees for technical services as payments for “managerial or technical or consultancy services, including the provision of services of technical and other personnel” (DTAA, 2011). These types of services are often required for the establishment of new manufacturing facilities in developing countries. Royalties are similarly important, including “the right to use industrial, commercial, or scientific equipment, or for information concerning industrial, commercial, or scientific experience” as is common in joint ventures and licensing arrangements (DTAA, 2011).

Given the development status of the two countries, it is much more likely that India invests in Ethiopia than the reverse. But the 2011 DTAA still benefits both parties: Indian MNCs save on tax costs and enjoy better access to information when investing in Ethiopia. The FDI then boosts the Ethiopian economy through the strengthening of domestic industry.

3.5.3. Rwanda

Rwanda’s development strategy is broader than that of Ethiopia and includes support for both the manufacturing and services sectors (Reynolds, 2018). Though its Vision 2050 initiative and National Strategy for Transformation set the ambitious goal of becoming a high-income nation, Rwanda has done comparatively little to encourage FDI (Reynolds, 2018). As a member of the East African Community, Rwanda has, to the detriment of larger international investors, favored the investment of its neighbors (Reynolds, 2018). As such, it does not currently have a DTAA with India.

3.5.3.1. Development status

Though Rwanda boasts strong GDP growth of over 7% annually over the past two decades, the country remains far from its goal of high- or even middle-income status (ITA, 2020b). Rwanda is predominantly rural, and over 75% of the population is employed in agriculture (CIA, 2021d). Some 39% of Rwandans live below the poverty line, and as of 2019, per capita income was just \$818 (CIA, 2021d; ITA, 2020b). Like Ethiopia, Rwanda enjoys favorable projections of human capital, with over 60% of the population under age 24 and improving mortality metrics (CIA, 2021d; World Bank, 2016). Though shifting towards NCDs, Rwanda continues to struggle with major infectious diseases (CIA, 2021d).

The government’s focus on manufacturing and services growth has yielded results – in 2019, the economy grew more than 9% (ITA, 2020b). Over the past decade, “the percentage of foreign assistance in the country’s annual budget has dropped from over 80%...to 39.5% in the 2020/2021 national budget” (ITA, 2020b). This self-sufficiency is thanks to the growth of the

services sector, which by 2017 accounted for more than 51% of GDP (CIA, 2021d). As of 2020, Rwanda ranked relatively high on the World Bank’s Ease of Doing Business Index at 38th – the second-best in sub-Saharan Africa (ITA, 2020b).

Economic outlooks for Rwanda are generally positive, citing low inflation, a reputation for low corruption, and a relatively low external debt-to-GDP ratio (ITA, 2020b). However, because of a reliance on imports, “the Rwandan government faces chronic and large current account deficits” (ITA, 2020b). In 2019, imports exceeded \$2.7 billion, an increase of over 10% from the previous year due to infrastructure projects and industry development that require capital and intermediary goods (ITA, 2020b). The government views the deficit as a short-term evil necessary for the development of domestic capacity.

3.5.3.2. Pharmaceutical industry

According to a 2016 report by USAID, Rwanda’s pharmaceutical manufacturing capability is “fledgling” with “limited capacity” for only “non-complex products” (p.1). Like other developing countries, Rwanda remains reliant on imports from India and China (Uwizeyimana et al., 2021, p.3). In 2019, Rwanda spent over \$97 million on drug imports, and estimates for 2024 are as high as \$102.5 million (Uwizeyimana et al., 2021, p.3). Facing foreign exchange shortages, the Rwandan government supports local pharmaceutical manufacturing as a way to reduce import expenses (Uwizeyimana et al., 2021, p.3).

Although liberalizing change in the last two decades has made conducting business easier for both locals and foreigners, the pharmaceutical sector has not yet caught on (Uwizeyimana et al., 2021, p.3). Rwanda still struggles with “a huge investment gap in the pharmaceutical sector,” relying instead on state-owned procurement agencies who typically purchase abroad (Uwizeyimana et al., 2021, p.3). As of 2018, there was no local production by MNCs (see: *Case Studies B2 and B4*) (US Department of Commerce [USDOC], 2018).

3.5.4. India

Over the past thirty years, India’s pharmaceutical industry has grown from nearly nonexistent to now the world’s third-largest industry by volume (“India’s generics,” 2012, p.41). Exports account for roughly \$9 billion of the industry’s \$20 billion valuation (“India’s generics,” 2012, p.41). Of total Indian exports to Africa, drugs represent 11.1% (“India’s generics,” 2012, p.41).

Unlike other developing countries, India’s pharmaceutical industry is heterogeneous and includes several large, export-oriented MNCs (Chaudhuri &

West, 2015, p.27). India is the world's primary provider of generic medicines and manufacturers straight for all minerals, including haematinics like folic acid ("India's generics," 2012, p.41; Monterrosa et al., 2018, p.7).

Indian investment in Africa began in 1977 with the expansion of Ranbaxy Laboratories into Nigeria ("India's generics," 2012, p.41). Since then, cooperation has grown, with Africa now accounting for 16% of all Indian pharmaceutical exports ("India's generics," 2012, p.41). Cipla, India's second-largest pharmaceutical company, is the continent's largest supplier of anti-malarial drugs ("India's generics," 2012, p.41). According to news source African Business, "at an India-African conference held in Addis Ababa in May [2011], Prime Minister Manmohan Singh announced that India will create a \$700 million line of credit to help in training and building new institutions across Africa" ("India's generics," 2012, p.41). Despite trade agreements and capacity building, though, Indian medicines sold in African import markets are generally more expensive than those available in the domestic Indian market, suggesting local production is favorable for access (Chaudhuri & West, 2015, p.33).

4. Empirical Methodology

Recall our hypotheses (a) tax incentives effectively induce greater foreign direct investment in East Africa, including pharmaceutical production, and (b) local pharmaceutical production in East Africa provides better access to essential drugs like haematinics as measured by anemia prevalence in children under five. To facilitate our empirical test of the latter, the former is assumed to be true based on the literature. Data analysis was conducted using Demographic and Health Surveys for Ethiopia and Rwanda. First, we performed ordinary least-squares (OLS) regressions to explore the determinants of hemoglobin levels and anemia. We then ran a difference-in-differences (DID) regression to estimate the causal effect of the 2011 Ethiopian DTAA on anemia levels of children under five.

4.1. Data sources

This study used four datasets from the Demographic and Health Surveys. For both the treatment and control groups, Ethiopia and Rwanda, data was needed from before and after the intervention. The intervention being the 2012 implementation of the 2011 Ethiopian-Indian DTAA, the datasets selected were the following:

- 2011 Ethiopian Demographic and Health Survey, Children's Recode

- 2016 Ethiopian Demographic and Health Survey, Children's Recode
- 2010 Rwandan Demographic and Health Survey, Children's Recode
- 2015 Rwandan Demographic and Health Survey, Children's Recode

Though ideally the before/after datasets would be collected in the same year, the DHS program performs surveys in cycles which vary by country. DHS surveys use a "multistage stratified cluster sampling technique" explained in detail in each respective report (Worku, Tesema, & Teshale, 2020, p.2).

4.2. Data management and analysis

We conducted background research using electronic databases, including Google Scholar, EBSCO Host, and Academic Search Complete, among others. After identifying an initial set of applicable studies, we then used a "snowballing" technique to locate additional sources – tracing backward references cited in the initial articles and forward tracing works that cited the original (van Essen, van Oosterhout, & Heugens, 2013, p.536). We also used data visualization tools available through the World Health Organization, World Bank, and Institute for Health Metrics and Evaluation.

Data extraction, recoding, and analysis were performed using STATA version 16 software. Using the 95% confidence level, p-values of ≤ 0.05 and $|t\text{-stats}|$ of ≥ 2 were considered thresholds of statistical significance. Because the study was conducted using publicly available survey data, ethical approval and participant consent were not required. We did, however, request and receive permission from the DHS Program to download and use the data for secondary analysis.

4.3. Ordinary least-squares (OLS) regressions

We first performed OLS regressions to explore the determinants of hemoglobin and anemia levels. This provided a baseline understanding of country, region, and year fixed effects. This preliminary analysis supports the robustness of our later DID regressions.

4.3.1. Study variables

Our selection of variables is based on research performed by health experts in the United States and Ethiopia. Though not exhaustive, our variable selection accounts for many of the major determinants of anemia.

4.3.1.1. Outcome variables

OLS regressions were performed using three types of outcome variables for children under five: (i) hemoglobin level, (ii) split moderate and severe anemia,

Table 3. Description and measurement of the outcome variables.

Outcome variables and their description/categorization	
Child hemoglobin level	Hemoglobin level adjusted by altitude in g/dl with one implied decimal ¹
Child moderate anemia	Recoded from the DHS discrete variable “anemia level”; “1” if hemoglobin levels between 7.1 g/dl and 9.9 g/dl, “0” if not.
Child severe anemia	Recoded from the DHS discrete variable “anemia level”; “1” if hemoglobin levels below 7.0 g/dl, “0” if not.
Child severe or moderate anemia	Recoded from the DHS discrete variable “anemia level”; “1” if hemoglobin levels below 9.9 g/dl, “0” if not.

Notes: ¹USAID, 2013, p.21

Table 4. Description and measurement of the independent variables.

Independent variables and their description/categorization	
Individual level variables	
Child birth order	A child’s order of birth among those in its family.
Family size	Total number of children in a child’s family.
Mother hemoglobin level	Hemoglobin level of the child’s mother adjusted by altitude in g/dl with one implied decimal.
Child age	Child’s age in months.
Child weight-for-height percentile	Calculated using the CDC Standard Deviation-derived Growth Reference Curves derived from the NCHS/FELS/CDC Reference Population with two implied decimal places ¹ .
No education	Recoded from the DHS discrete variable “highest educational level attended”; “0” if some education, “1” if no education.
Poor	Recoded from the DHS discrete variable “wealth index,” a composite measure of a household’s cumulative living standard as measured by asset ownership ¹ . “0” if “richest,” “richer,” or “middle,” “1” if “poorest” or “poorer”.
Community-level variables	
Residence	Recoded from the DHS discrete variable “de facto type of place of residence”; “0” if “urban”, “1” if “rural”.
Region	De facto region of residence.

Notes: ¹USAID, 2013, p.78, 18.

and (iii) combined moderate and severe anemia. Hemoglobin level was provided by the DHS reports as a continuous measure adjusted for altitude in g/dl with one implied decimal (USAID, 2013, p.21). From a child’s reported hemoglobin level, the DHS reports then created a new discrete variable “anemia level”, which categorizes children as having mild, moderate, or severe anemia based on the following thresholds:

- Severe: Below 7.0 g/dl
- Moderate: Between 7.1 g/dl and 9.9 g/dl
- Mild: Between 10.0 g/dl and 10.9 g/dl (USAID, 2013, p.79)

From this DHS variable we created three binary

variables: (i) child severe anemia (ii) child moderate anemia (iii) child severe or moderate anemia, where 1 indicates a child whose hemoglobin falls into the relevant threshold and 0 indicates one who does not. Outcome variables are described in *Table 3*.

4.3.1.2. Independent variables

Our study included seven individual and two community-level factors as independent variables as described in *Table 4*. OLS regressions are used to confirm these variables’ correlation with anemia for later inclusion as protections against endogeneity in the DID

regressions. Independent variables are described in Table 4.

4.4. Difference-in-difference (DID) regressions

Sometimes referred to as the “controlled before-and-after study,” the difference-in-differences (DID) model “is a quasi-experimental design that makes use of longitudinal data from treatment and control groups to obtain an appropriate counterfactual to estimate a causal effect” (Mailman School, n.d.). It is often used to estimate the effect of an intervention by comparing changes in outcome over time between an intervention and control group, especially “when randomization on the individual level is not possible” (Mailman School, n.d.). By accounting for differences between the treatment and control group the beginning of the study period, the DID method “removes biases in post-intervention period comparisons...that could be the result from permanent differences between those groups” (Mailman School, n.d.). This technique is shown graphically in Figure A5.

Our study uses the Ethiopian and Rwandan DHS datasets as repeated cross-sectional data. Recalling that our treatment is the 2011 Ethiopian-Indian DTAA, a child’s country determines its treatment status; “Treat,” $T=0,1$, where 0 indicates Rwandan children (control group), and 1 indicates Ethiopian children (treatment group). Children are observed in two time periods; “After,” $t=0,1$ where 0 indicates pre-treatment (2010 in Rwanda and 2011 in Ethiopia) and 1 indicates post-treatment (2015 in Rwanda and 2016 in Ethiopia). The basic DID equation is

$$(1) \quad Y = \beta_0 + \beta_1(t) + \beta_2(T) + \beta_3(t \times T) + \varepsilon$$

where Y is the outcome variable, β_0 is a baseline average of the control group, β_1 is the time trend of the control group, β_2 is the difference between the treatment and control pre-intervention, and ε is an error term containing all determinants of Y omitted from the model (Mailman School, n.d., Albouy, n.d., p.1). The coefficient of interest is β_3 , which estimates the effect of the treatment on the outcome. β_3 is the DID estimator calculated as “the difference in average outcome in the treatment group before and after treatment minus the difference in average outcome in the control group before and after treatment” (Albouy, n.d., p.3).

4.4.1. Required assumptions

The DID method requires three assumptions. Firstly, the error term must, on average, be zero; $E(\varepsilon) = 0$. Secondly, the error term must be uncorrelated with all other variables in the equation; $Cov(x, \varepsilon) = 0$. Most

importantly, the DID method relies on the parallel trends assumption, which states that “in the absence of treatment, the unobserved differences between treatment and control groups are the same over time” (Mailman School, n.d.). Should any of these assumptions not hold, then the β_3 estimator cannot confidently be said to be unbiased. Because these assumptions refer to unobservable qualities, they may be difficult or impossible to verify (see: 6. Discussion) (Albouy, n.d., p.4).

5. Results

Having found statistically significant correlations between mother hemoglobin level, child age, child weight-for-height percentile, parent education, wealth status, and residence, our OLS regressions support the existing literature on the determinants of anemia. Our DID regressions, however, provided inconclusive results regarding the efficacy of the DTAA in reducing anemia.

5.1. OLS regressions

A 2018 study conducted by Ejigu, Wencheke, and Berhane using the 2011 Ethiopian DHS dataset found “education level, age, wealth index, [and] BMI...to be significant predictors of anemia prevalence” (p.1). A similar study conducted by Worku, Tesema, and Teshale in 2020 using the 2016 Ethiopian DHS dataset found that living in a rural area is also significantly associated with anemia prevalence (p.2). Because anemic mothers are more likely to have anemic children, we also include the mother’s hemoglobin level (Monterrosa et al., 2018, p.1). To these variables we added child birth order, family size, and child age to account for potential endogeneity related to family wealth, access to proper nutrition, or biological development. The OLS regressions are for the equation

$$(2) \quad Y = I_0 + I_1X_1 + I_2X_2 + I_3X_3 + I_4X_4 + I_5X_5 + I_6X_6 + I_7X_7 + I_8X_8 + \varepsilon$$

where I_0 is a constant, I_1 is the coefficient for child birth order, I_2 is the coefficient for family size, I_3 is the coefficient for mother hemoglobin level, I_4 is the coefficient for child age, I_5 is the coefficient for child weight-for-height percentile (substituted for BMI), I_6 is the coefficient for no education, I_7 is the coefficient for poor, I_8 is the coefficient for residence, and ε is an error term containing all determinants of Y omitted from the model. Table 5 shows the coefficients when Y is the combined binary variable for moderate or severe anemia, though results were similar for regressions using child

Table 5: Determinants of anemia.

	Dependent variable: Child has moderate or severe anemia			
	(1)	(2)	(3)	(4)
Child birth order	.01178*	.00804	-.00302	-.00273
Family size	.00077	.00082	.0005	.00026
Mother hemoglobin level	-.00313*	-.00303*	-.0022*	-.00211*
Child age	-.00272*	-.00257*	-.00232*	-.00231*
Child weight-for-height percentile	-.00001*	-.00002*	-.00001*	-.00001*
No education	.05916*	.0302*	.02304*	.02563*
Poor	.05011*	.05347*	.04569*	.04424*
Residence	-.00482	.00484	.02689*	.0288*
Observations				
Country fixed effects	No	Yes	Yes	Yes
Region fixed effects	No	No	Yes	Yes
Year fixed effects	No	No	No	Yes

Notes: Standard errors clustered at the DHS clustering level. Asterisk (*) indicates statistical significance at the 95% confidence interval.

hemoglobin level, child moderate anemia, and child severe anemia.

Regressions were performed four times, each time adding a level of control against unobservable characteristics. Column (1) shows the coefficients of our various independent variables with no attention to fixed effects, making these values subject to endogeneity concerns. In Column (2), we add the binary variable “Country,” which assigns “0” if a child is Ethiopian and “1” if a child is Rwandan. The OLS regression equation is thus adjusted to

$$(3) \quad Y = I_0 + I_1X_1 + I_2X_2 + I_3X_3 + I_4X_4 + I_5X_5 + I_6X_6 + I_7X_7 + I_8X_8 + I_9X_9 + \varepsilon$$

where I_9 is the coefficient for country. In Column (3), we add the discrete variable “Region,” which accounts for the non-temporal, unobservable characteristics unique to each of Ethiopia’s nine geographical regions and two administrative cities using the Tigray region as the comparison (CSA & ICF, 2016, p.2). At this point, residence becomes statistically significant, aligning with the research performed by Worku, Tesema, and Teshale. The regression equation is thus adjusted to

$$(4) \quad Y = I_0 + I_1X_1 + I_2X_2 + I_3X_3 + I_4X_4 + I_5X_5 + I_6X_6 + I_7X_7 + I_8X_8 + I_9X_9 + I_{10}X_{10} + \varepsilon$$

where I_{10} is the coefficient for region. In Column (4), we add the variable “Year,” which accounts for the specific effects of the study years using 2010 as the comparison. The regression equation is adjusted one final time to

$$(5) \quad Y = I_0 + I_1X_1 + I_2X_2 + I_3X_3 + I_4X_4 + I_5X_5 + I_6X_6 + I_7X_7 + I_8X_8 + I_9X_9 + I_{10}X_{10} + I_{11}X_{11} + \varepsilon$$

where I_{11} is the coefficient for year. This final column is the most robust, as it accounts for three types of fixed effects that may affect endogeneity. We find that, as the literature suggested, mother hemoglobin level, child weight-for-height percentile, no education, poor, and residence all have statistically significant effects on a child’s likelihood of being moderately or severely anemic. We also find that a child’s age is statistically significant, though it was not mentioned in the literature reviewed. This prepares us for our DID regression, where we include these variables as protections against endogeneity having confirmed their relevance.

5.2. DID regressions

We performed the DID regression three times, each time adding a level of control against endogeneity. Table 6 shows the coefficients when Y is the combined binary variable for moderate or severe anemia. Column (1) shows the coefficients of for the binary variables “Treat” and “After”, which correspond to T and t, respectively. This first regression uses the basic DID equation

$$(1) \quad Y = \beta_0 + \beta_1(t) + \beta_2(T) + \beta_3(t \times T) + \varepsilon$$

where β_3 is the variable of interest and includes no controls for fixed effects, making these values subject to endogeneity concerns. In Column (2), we add independent variables I_1 through I_8 . We include child birth order and family size for consistency, even though they were not found to be statistically significant at the 95% confidence interval. The DID regression equation is thus adjusted to

$$(6) \quad Y = \beta_0 + \beta_1(t) + \beta_2(T) + \beta_3(t \times T) + I_1X_1 + I_2X_2 + I_3X_3 + I_4X_4 + I_5X_5 + I_6X_6 + I_7X_7 + I_8X_8 + \varepsilon$$

Table 6: 2011 Ethiopian-Indian DTAA effects.

	Dependent variable: Child has moderate or severe anemia		
	(1)	(2)	(3)
Treat	.15081* (.007)	.05283* (.009)	.10199* (.011)
After	.00552 (.004)	.00988 (.008)	.1167 (.009)
Treat x After	.05288* (.01)	.04316* (.013)	.03478* (.013)
Observations			
Independent variables I_1 through I_8	No	Yes	Yes
Region fixed effects	No	No	Yes

Notes: Standard errors clustered at the DHS clustering level and shown in parentheses. Asterisk (*) indicates statistical significance at the 95% confidence interval.

In Column (3), we add the discrete variable Region to account for fixed effects. The DID regression equation is adjusted for a final time to

$$(7) Y = \beta_0 + \beta_1(t) + \beta_2(T) + \beta_3(t \times T) + I_1X_1 + I_2X_2 + I_3X_3 + I_4X_4 + I_5X_5 + I_6X_6 + I_7X_7 + I_8X_8 + I_{10}X_{10} + \varepsilon$$

This final column is the most robust. Results were similar when DID regressions were performed for the dependent variables Child Severe Anemia and Child Moderate anemia, though more dramatic in the latter. The last value in the third column suggests that an Ethiopian child post-DTAA had a .03478 greater probability of being anemic than a Rwandan child post-DTAA. Contrary to our primary hypothesis, the results in Table 4 show a strong *positive* correlation between the post-DTAA time period and probability of moderate and severe anemia. Despite this correlation, a number of concerns prevent an interpretation of this relationship as causal. The results may only be declared inconclusive.

6. Discussion

Our results may be uncertain for a variety of reasons including violations of statistical assumptions and or local conditions. These factors introduce both positive and negative bias, obscuring our final outputs.

6.1. Violations of statistical assumptions

Our statistical assumptions described in section 4.4.1. may not have been met by our quasi-experimental design, introducing bias to both our OLS and DID regressions. Our concerns are consistent with empirical challenges faced by similarly-designed studies.

6.1.1. Reverse causality and omitted variables

Our OLS regressions may violate assumptions $E(\varepsilon) = 0$ and $\text{Cov}(x, \varepsilon) = 0$. The former is challenged by potential reverse causality. Horton & Ross find that anemia may affect metabolic systems, therefore affecting a child's weight-to-height percentile (2003, p.63). As a risk factor for infant mortality and delayed development, anemia may also contribute to poverty via additional direct and indirect healthcare expenditures (Van Ejik et al., 2007 as cited in Schady, 2012, p.887; Horton & Ross, 2003, p.53; Alzácar, 2012, p.49).

Omitted variables may violate both assumptions $E(\varepsilon) = 0$ and $\text{Cov}(x, \varepsilon) = 0$ and introduce positive bias. There are likely several determinants of child moderate or severe anemia that will naturally be correlated with our other independent variables, such as nutritional intake (Acemoglu, Johnson, & Robinson, 2001, p.1379; Ejigu, Wencheke, & Berhane, 2018, p.13). Other relevant variables may include instinal worm infection and malaria (Bobonis, Miguel, & Puri-Sharma, 2006, p.4; Ejigu, Wencheke, & Berhane, 2018, p.13; White, 2018, p.1). Omission of potentially correlated variables was cited as a weakness of Ejigu, Wencheke, & Berhane's regression model (2018, p.13).

6.1.2. Parallel trends assumption

Recall that DID regressions require the parallel trends assumption, wherein changes in the treatment group over time are expected to be the same as the control group if no treatment were administered. This may be violated by pre-treatment trends differences, extraneous events, and or irrelevance of variables of interest. According to professor of economics David Albouy, "the failure of the parallel trend assumption may

in fact be a relatively common problem in many program evaluation studies” (n.d., p.1).

6.1.2.1. Pre-treatment trends differences

The parallel trends assumption suggests that “the untreated units provide the appropriate counterfactual of the trend that the treated units would have followed if they had not been treated – that is, that the two groups would have had parallel trends” (McKenzie, 2020). While the two groups do not have to be similar in absolute terms, their changes over time must be comparable. This implies developmental similarities between the two groups, including external factors like environmental, social, and economic conditions.

As shown in *Figure A6*, the parallel trends assumption appears to hold in the prevalence of anemia among children under five for Ethiopia and Rwanda. The assumption holds because both countries show a downward trend in prevalence, but it’s important to note that Ethiopia’s absolute rates are considerably higher (World Bank, 2016). According to a 2019 study by Kahn-Lane and Lang, “DID will generally be more plausible if the treatment and control groups are similar in levels to begin with, not just in trends” (McKenzie, 2020).

Figures A7, A8, and A9 show determinants of anemia for which the parallel trends assumption does not hold due to differences before the study period (pre-2010). Malaria, a major cause of anemia, was highly variable in both countries in the early 2000s (White, 2018; World Bank, 2018a). Urbanization trends and persistence to the last grade of primary school were also dissimilar, and were found in both the literature and our OLS regressions to be correlated with anemia (World Bank, 2019c; World Bank, 2018b; Worku, Tesema, & Teshale, 2020, p.2; Ejigu, Wencheke, & Berhane, 2018, p.1). Failure of the parallel trends assumption for these correlates may bias the DID regression for anemia itself.

6.1.2.2. Extraneous events

Our study may violate the parallel trends assumption if unexpected measures were introduced in either the treatment or control country during the period of observation.

For example, the 2011 Kigali Special Economic Zone (KSEZ) Law created a regulatory body to oversee the development and promotion of SEZs in Rwanda (Saunders, 2019). The KSEZ offers special access to infrastructure, tax incentives, customs exemptions, and preferential regulatory treatment that is attractive to industry, especially among the Chinese (Steenbergen & Javorcik, 2017, p.2; Saunders, 2019). This has been made possible in part by the government’s proper

handling of foreign aid, 58% of which was channeled through the national government by 2010 compared to just 20% in most post-conflict countries (Savchuk, 2014). These business environment improvements and subsequent industrial growth could have increased per capita income in Rwanda, improving household wealth that is negatively correlated with anemia (Ejigu, Wencheke, & Berhane, 2018, p.1). This would introduce negative bias into our model. It appears that the SEZs did not result in local pharmaceutical manufacturing specifically, since as of 2018, there were still no local producers in Rwanda (USDOC, 2018).

In Ethiopia, ongoing conflicts with neighbors Eritrea and Somalia may have contributed to poverty, food scarcity, and other negative public health consequences. Though formally ended with the signing of the Algiers Peace Agreement in 2000, the Ethiopian-Eritrean border dispute remains hostile due to continued support of rebel groups as proxies (Gebreluel & Tronvoll, 2013). In 2013, Eritrea was reported by the UN to have paid political agents linked to Islamist militants to influence the Somali government, whom Ethiopia had sent troops to support (Maasho, 2013). Children living in affected regions may suffer health impacts from instability including lower height-for-age and poor nutritional status, which would introduce negative bias into our model (Barker, 1998 as cited in Arkesh, Lucchetti, & Thirumurthy, 2011, p. 2). It is therefore possible that the 2011 Ethiopian-Indian DTAA did result in greater local pharmaceutical manufacturing, but that the benefits of access were offset by larger events with negative health impacts.

6.1.2.3. Drug access not a primary determinant of anemia

It may be that the price of drugs to treat anemia is much less important than the lifestyle conditions that cause it. If access to haematinics is not a primary determinant of anemia, then any local production effects of the DTAA would be irrelevant. We assume that the DTAA benefits consumers via improved access from local production. If the DTAA were to have no effect, then our results would purely reflect extraneous events.

Though Chaudhuri et al. (2010), Mujinja et al. (2014), and Ewen et al. (2017) found that local production improved rural and low-income access to essential medicines, it may still be true that such access is not a primary determinant of anemia. Although wealth, for example, which is correlated with anemia and is a proxy for purchasing power (suggesting price sensitivity), wealth is also likely correlated with nutritional status, education, residence, and access to

healthcare. These may be more significant than access and are not affected by the DTAA.

Residence and access to healthcare, for instance, are particularly important for anemia. Our OLS regressions show that the Affar region, for example, where 91% of the population is rural, is significantly correlated with a higher probability of moderate anemia (Ethiopia Sheep and Goat Productivity Improvement Program [ESGPIP], n.d.). Since the 1990s, the region has experienced a major drought every two to three years, affecting access to nutrition (ESGPIP, n.d.). Similar issues are seen in the Somali region and Dire Dawa administrative city (UNICEF, 2019; Fuller, 2019). Distance to health facilities is higher in rural areas and is recognized as a critical barrier to maternal care and iron supplementation uptake (Sabine & Oona, 2009 as cited in Manang, 2019; Simuyemba et al., 2020, p.1). Because anemia is especially prevalent among pregnant women and may be passed to the child, maternal care is critical to anemia prevention (Schady, 2013, p.887; Monterrosa et al., 2018, p.1). Though the development of industry may increase per capita income over time, the FDI resulting from the growth of the pharmaceutical sector specifically is unlikely to make significant impacts on population distributions between rural and urban areas. In other words, local pharmaceutical manufacturing may only address some pieces of the puzzle, and not necessarily the most important ones.

6.1.2.4. DTAA has no effect on FDI

Our study relies on the assumption that Hypothesis (a), tax incentives effectively induce greater foreign direct investment in East Africa, including pharmaceutical production, is true based on the literature. However, there are also several studies that have found this claim to be false. Again, if the DTAA were to have no effect, our results would purely reflect extraneous events.

A 2007 study by Neumeyer across developing countries found that DTAA only led to greater FDI among middle-income countries, not low-income countries like Ethiopia and Rwanda. A 2015 study by Shah & Qayyum similarly found that DTAA have no effect on FDI. Rather, the study explains, “market size, development level, trade openness, and human capital” are stronger determinants of FDI (Shah & Qayyum, 2015, p.1). The draw of double taxation avoidance may be offset by the deterrent of limited opportunity for tax evasion (Shah & Qayyum, 2015, p.1). A 2006 study by Egger et al. even found that DTAA have a negative effect on FDI, which might explain Rwanda’s favorable performance in our DID regression except for our

knowledge that Rwanda has (and had for the majority of the study period) no local pharmaceutical production (USDOC, 2018). Our assumption that the 2011 Ethiopian-Indian DTAA would be effective in inducing FDI may have been premature given the inconclusively of the literature.

6.2. Local conditions

It may also be that the Ethiopian-Indian DTAA did result in greater local pharmaceutical manufacturing, but that comparative market immaturity in Ethiopia as compared to Rwanda prevented the realization of benefits presented in the literature.

6.2.1. Economies of scale

For local pharmaceutical production to improve access to medications via lower prices, firms must have access to economies of scale (Kaplan & Laing, 2005, p.7). Firms in sub-Saharan Africa are disadvantaged by higher input, logistics, and financing costs which can be offset only by volume (Chaudhuri & West, 2014, p.24). A 2004 modelling study by Guimier, Lee, & Grupper confirms the sensitivity of domestic manufacturing to market share.

The Rwandan pharmaceutical market is consolidated among just two types of players, government procurement agencies and private importers (USAID, 2016, p.1). With greater market share, the government may therefore be able to negotiate better pricing in international tenders, which could translate into better access via lower prices or better availability for patients. By contrast, Ethiopia’s pharmaceutical market is more liberalized and heterogenous, preventing the consolidation of market share necessary for economies of scale.

6.2.2. Regulatory environment

Although Ethiopia’s regulatory budget is quite large for a developing country, Rwandan regulatory efforts may be more efficient and effective (Conway et al., 2019, p.7).

6.2.2.1. Protections against counterfeit drugs

Robust protections against counterfeit drugs in Rwanda may boost patient confidence, encouraging individuals to visit health care facilities. A 2013 study by Binagwaho et al. found that among the 17 countries observed, “Rwanda was the only African nation whose samples did not include any falsified products” (p.1). A 2008 study by Nsimba found that counterfeit drugs in developing countries reduce patient confidence in healthcare professionals and or modern medicine. Greater confidence in healthcare may lead Rwandans to

attend health facilities more often, allowing them to know their health status and medicate as necessary.

6.2.2.2. National insurance programs

Universal health coverage is more developed in Rwanda than in Ethiopia. Though Ethiopia has made efforts to improve the national insurance system, introducing pilot programs in 13 districts in 2012, full implementation is still in its intermediate stages (USAID, n.d.). By contrast, Rwanda's community-based health systems were internationally recognized as early as 2014 as a model of success in achieving universal health coverage (Management Sciences for Health [MSH], 2016; MSH, 2014). Between 2003 and 2013, health insurance coverage expanded from just 7% of the target population to 74% (MSH, 2016). Benefits include protections against out-of-pocket costs and "better access to drugs" (MSH, 2016). Like protections against counterfeit drugs, this insurance system may lead Rwandans to attend health facilities more often, allowing them to (a) know their health status and (b) afford relevant medicines.

6.2.2.3. Intellectual property law

As described in section 3.3.4., Rwanda is an outlier among African countries, having fully aligned its intellectual property law with that of TRIPS and other international conventions (Owoeye, 2014, p.215). Rwanda also actively exercises the benefits of the Paragraph 6 System – a TRIPS flexibility mechanism given legal status in 2005 (Kampf, 2015, p.2, 16). The Paragraph 6 System provides a special type of compulsory license for WTO member states producing medicines for to meet the needs of other members (Kampf, 2015, p.4). Importantly, however, the process "requires domestic action on the part of beneficiary countries to identify and communicate relevant needs for imports...[to] foreign producers" (Kampf, 2015, p.16). The system therefore effectively creates an international communication system for procurement, which may result in lower prices by expanding trade opportunities (Kampf, 2015, p.16). While Ethiopia may be eligible to

use this system as a low-income country, there is little evidence of it doing so in the literature.

6.2.3. Infrastructure

With a geographical area 41 times smaller than that of Ethiopia, Rwanda has an advantage in the development of infrastructure (CIA, 2021a; CIA, 2021d). Road coverage, airport construction, and other transportation infrastructure is a significantly smaller development task. Because of its size, the "urban bias" in essential medicine distribution described by Mujinja et al. may be less of a barrier to access in Rwanda (2014, p.1).

7. Conclusion

Our primary empirical test, our DID regression, was inconclusive due to various concerns over statistical assumptions. We can neither confirm nor reject our hypothesis that local pharmaceutical production as stimulated by the 2011 Ethiopian-Indian DTAA provides better access to essential drugs like haematinics. Our empirical concerns suggest that the determinants of anemia in children under five are many and interrelated.

7.1. Directions for future research

Future research may attempt to confirm the assumption of Hypothesis (a). Literature regarding the effects of DTAAAs on FDI is inconclusive, suggesting positive, negative, and zero correlation. There is also little research on the impact on pharmaceutical FDI specifically, which would be optimal for this study.

Other improvements may include the addition of other relevant independent variables (see: 6.1.1. *Reverse causality and omitted variables*) or the selection of a more geographically similar comparison country (see: 6.2.3. *Infrastructure*).

Appendix A

Figure A1

Relative Importance of Iron Deficiency Among Leading Risks of Years Lived with Disability (YLDs), 2015 Children Under Five

Both sexes, <5 years, 2015, YLDs per 100,000

	Ethiopia	Rwanda	Sub-Sah Africa	Brazil	Russian Federation	India	China	United States of America
Iron deficiency	1	1	1	1	1	1	1	3
Child underweight	2	8	3	7	6	2	6	20
Child wasting	3	9	4	8	7	3	7	21
Unsafe water	4	2	2	4	4	8	4	10
Vitamin A deficiency	5	7	6	6	18	7	9	15
Unsafe sanitation	6	3	5	5	5	9	5	8
Short gestation	7	4	7	2	2	4	2	1
Low birth weight	8	5	8	3	3	5	3	2
Handwashing	9	6	9	10	12	10	10	13
Lead	10	11	11	14	13	6	11	11

Source: IHME, 2019

Figure A2

Relative Prevalence of Anemia Among Leading Causes of Impairment, 2015 Children Under Five

Both sexes, <5 years, 2015, Prevalent cases per 100,000

	Ethiopia	Rwanda	Sub-Sah Africa	Brazil	Russian Federation	India	China	United States of America
Moderate anemia	1	2	1	2	2	1	2	2
Mild anemia	2	1	2	1	1	2	1	1
Severe anemia	3	5	3	6	13	4	12	20
Mild intellectual disability	4	4	5	5	4	3	4	3
Mild hearing loss	5	3	4	3	3	6	3	4
Borderline intellectual disability	6	6	6	12	6	5	7	6
Moderate hearing loss	7	7	7	10	7	9	6	12
Moderate vision loss	8	12	8	4	5	7	5	5
Moderate intellectual disability	9	10	11	11	8	8	9	7
Moderate epilepsy	10	9	10	7	10	11	10	8

Source: IHME, 2019

Figure A3

Relative Prevalence of Anemia Among Leading Causes of Impairment, 2015 All Age Groups

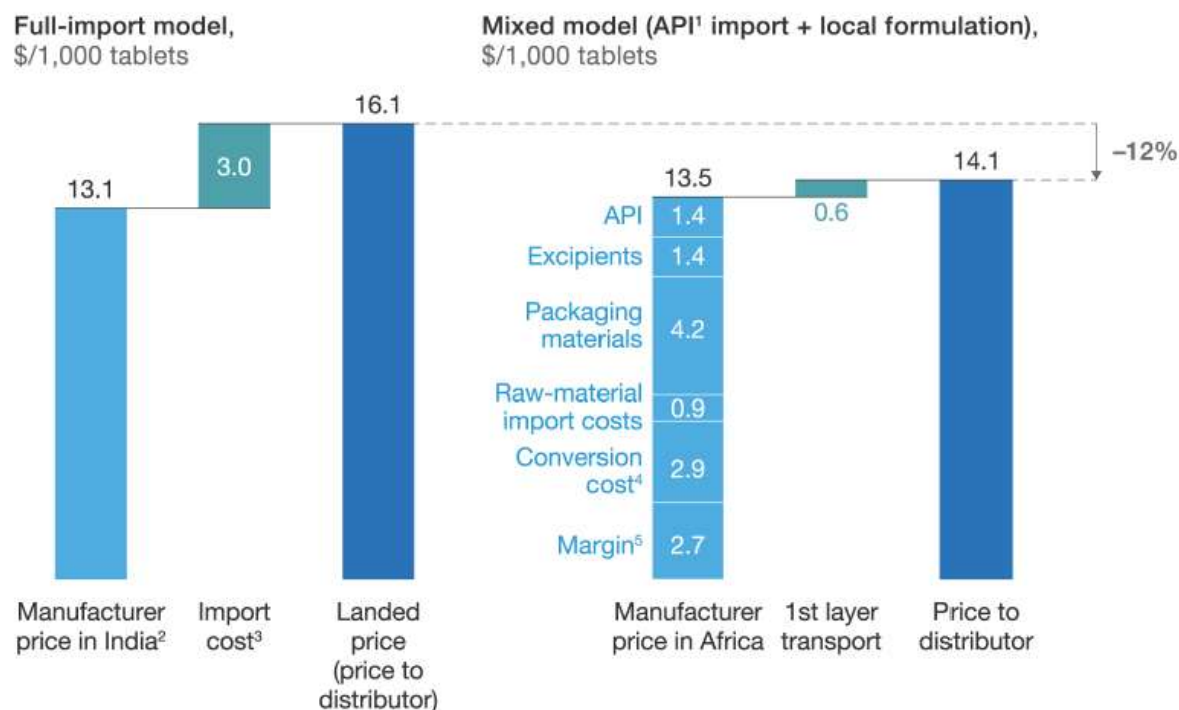
Both sexes, All ages, 2015, Prevalent cases per 100,000

	Ethiopia	Rwanda	Sub-Sah Africa	Brazil	Russian Federation	India	China	United States of America
Moderate anemia	1	2	1	3	6	1	7	4
Mild anemia	2	1	2	2	3	2	3	2
Mild hearing loss	3	3	3	1	1	3	1	1
Presbyopia	4	4	4	6	2	4	2	7
Moderate hearing loss	5	5	5	5	5	6	5	3
Moderate vision loss	6	7	8	4	4	5	6	5
Secondary infertility	7	11	6	7	7	7	4	8
Mild intellectual disability	8	6	9	10	10	8	9	10
Severe anemia	9	9	7	12	18	9	24	26
Moderately severe hearing loss	10	8	10	8	8	11	8	6

Source: IHME, 2019

Figure A4

Indian Import Versus Ethiopian Manufacturing

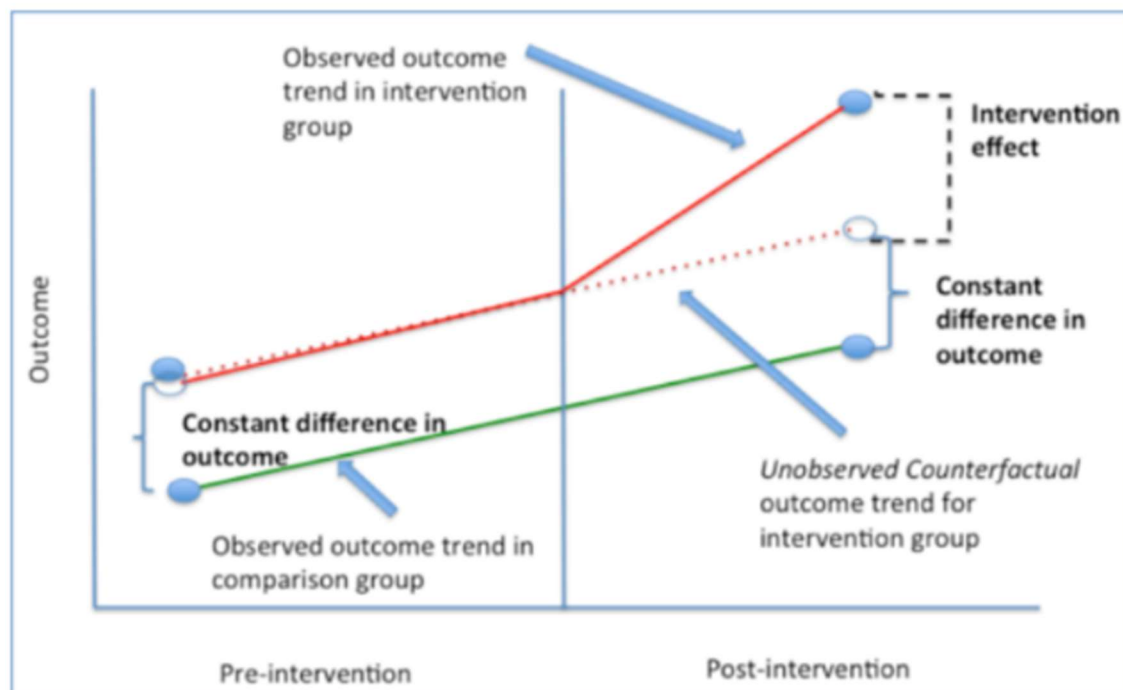


Note: This analysis is for 1 over-the-counter drug in Ethiopia; economics for other drugs may vary.

¹Active pharmaceutical ingredient. ²Per cleansheet model. ³Includes freight: 10%; duties: 5%; and value-added tax: 5% of API value. ⁴Includes direct labor, testing, facility, equipment, and overhead costs. ⁵Margin for local manufacturers ~20%.

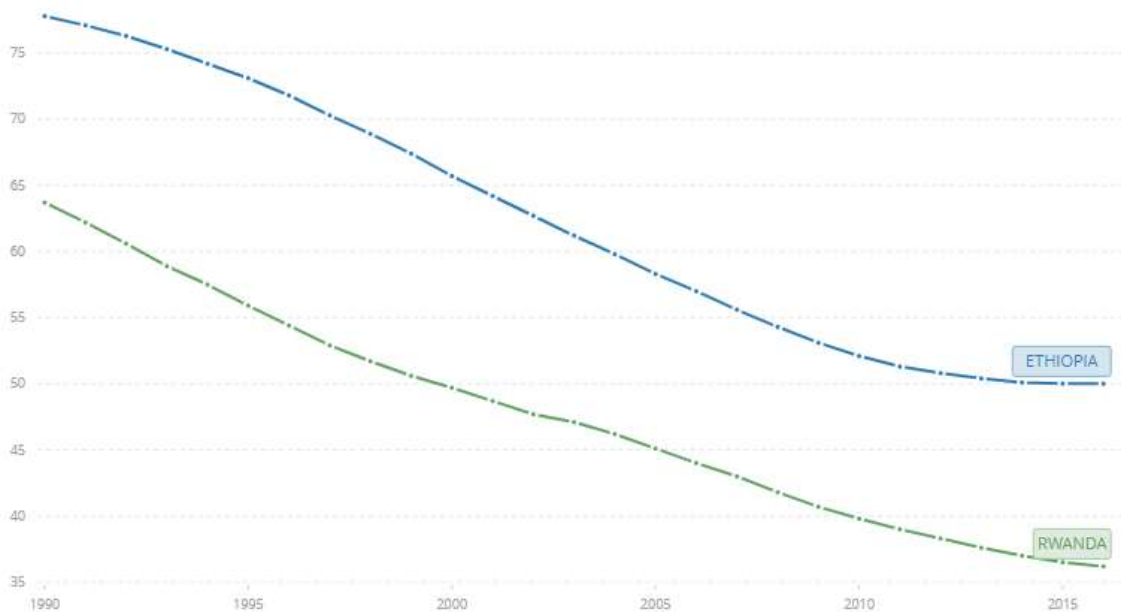
Source: Conway et al., 2019, p.6

Figure A5
Difference-in-Differences Estimation, Graphical Explanation



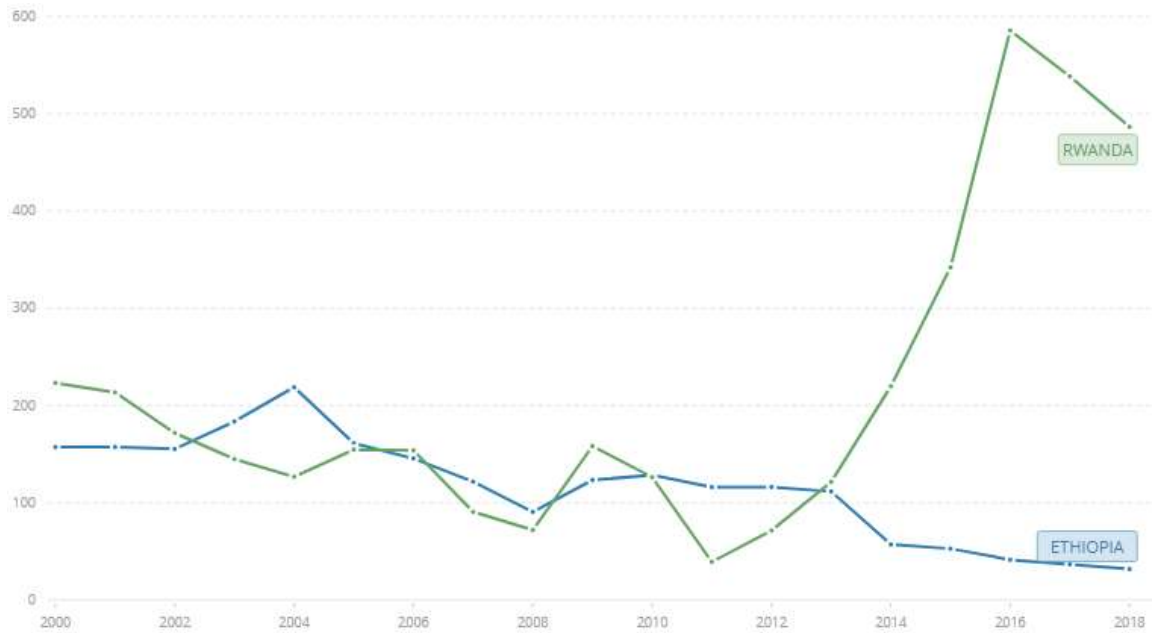
Source: Mailman School, n.d.

Figure A6
Prevalence of Anemia in Among Children (% of Children Under 5)



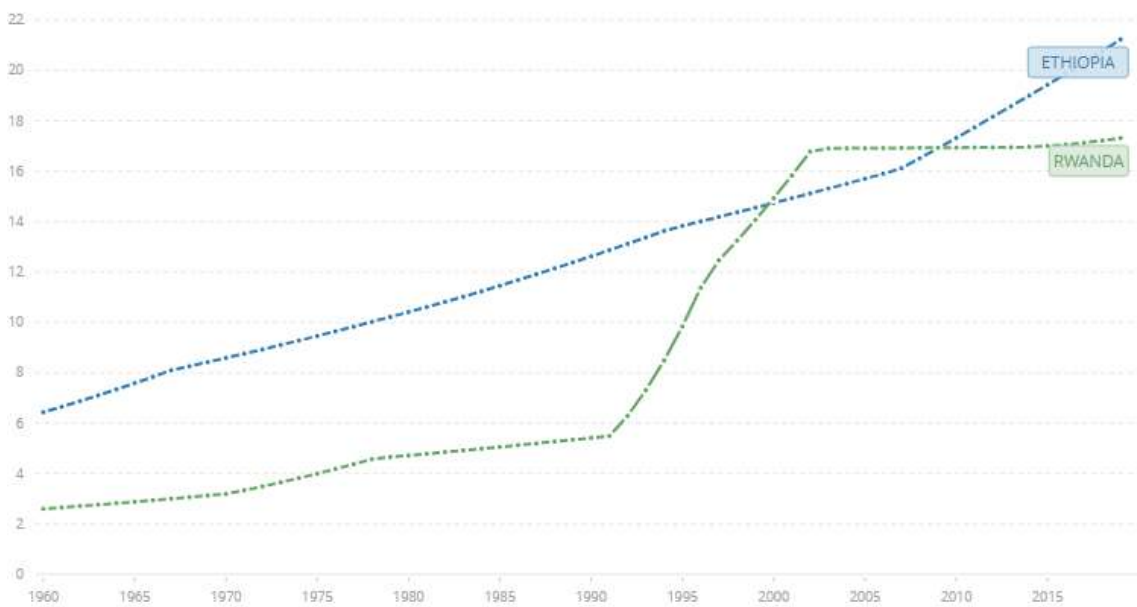
Source: World Bank, 2016

Figure A7
Incidence of Malaria (Per 1000 Population at Risk)



Source: World Bank, 2018a

Figure A8
Urban Population (% of Total Population)



Source: World Bank, 2019c

Figure A9

Persistence to Last Grade of Primary, Total (% of Cohort)



Source: World Bank, 2018b

Appendix B

Supplement B1. Production Variations

As illustrated in *Figure B1*, production can be classified by (a) investment type; local or import (b) branding type; branded or generic and (c) production stage; straight ingredients, premix, bulk finished products, finished branded products. This results in roughly 16 different scenarios, each of which have unique barriers to entry. The specific determination of all 16 scenarios is beyond the scope of this thesis, though the three classifications are useful for understanding the types of production possible.

SB1.1. Investment type

Local African producers currently hold just 20% of the market (Ford, 2017, p.40). Challenges to local production include donor preference for foreign products, lack of economies of scale, and insufficient infrastructure, among others (Ford, 2017, p.40; Chaudhuri & West, 2015, p.34; Holt et al., 2015, p.9). For MNCs, exporting is attractive as the lowest risk market entry mode. For African governments and citizens, however, the higher costs of drugs due to logistics costs and branding strain budgets and foreign exchange reserves. Dr. Mohammed Nuri, founder of Medtech Ethiopia, and Dr. Kambanda Rucwari, former director of Rwanda's LABOPHAR, explains these challenges in *Case Studies B1* and *B2*.

Local production in sub-Saharan Africa can be subdivided into two groups: (a) indigenous firms and (b) arrangements with foreign MNCs. The latter group can be further dissected into entry modes including contractual agreements, joint ventures, acquisitions, and wholly-owned subsidiaries (Gundelach & Hansen, 2020, p.179). In all these cases, local capacity is limited to manufacturing *after* the import of active pharmaceutical ingredients (APIs), with the exception of South Africa (Lartey et al., 2018, p.3; Owoeye, 2014, p.215; USAID, 2016, p.2).

In most cases of local production, the primary concern is cost competitiveness (Chaudhuri & West, 2015, p.24). Manufacturing in Africa presents several cost disadvantages, including lower productivity from lack of skilled labor, high materials cost, machinery imports, high fuel and electricity prices, and high financing costs (Chaudhuri & West, 2015, p.24). Critics of African production argue that the same amount of funding buys more medicine if imported (Chaudhuri & West, 2015, p.24). Others say that cost disadvantages are normal for developing industries and, with proper

government intervention, represent only short-term challenges (Chaudhuri & West, 2015, p.24).

While African governments tackle long-term regulatory and economic reform, MNCs seeking first-mover advantages can offset risk by choice of entry mode. Market entry strategy can be partially explained by the resource-based view, which suggests firms attempt to establish long-term competitive advantage through costly-to-copy resources (Gundelach & Hansen, 2020, p.176; Verbeke, 2009 as cited in Addae & Addae, 2013, p.29). In the context of African pharmaceuticals, these resources may include local distribution channels, relationships with supporting industries, or insight on local demand (Gundelach & Hansen, 2020, p.176-177). These assets act as counterforces to the challenges of developing markets, such complex regulation, small purchasing power, and information scarcity (Gundelach & Hansen, 2020, p.176). According to researchers I. Y. Addae and M. V. Addae, FDI may also be motivated by "market imperfections such as rising labor costs and enables firms to grow and expand by accessing demand" (Calvet, 1981 as cited in Addae & Addae, 2013, p.28). Choice of entry mode is also determined by transaction costs, or the costs of bargaining, information, and enforcement of contracts, which are high in developing markets due to institutional voids (Gundelach & Hansen, 2020, p.178; Khanna, Palepu, & Sinha, 2005, p.1).

In the case of high transaction costs and low firm resources, an MNC is likely to choose a less intensive, contractual entry mode like using agents, distributors, or licensing arrangements (Gundelach & Hansen, 2020, p.180). Agents and distributors help the MNC understand institutional barriers and local networks (Gundelach & Hansen, 2020, p.180; Addae & Addae, 2013, p.33). In licensing arrangements, an MNC contracts with local firms to produce proprietary products in exchange for a fee. These options are relatively inexpensive and avoid the risk associated with major FDI (Anderson & Gatignon, 1986; Hennart, 1989; Pan & Tse, 2000 as cited in Addae & Addae, 2013, p.35). However, reliance on a foreign partner presents risk of opportunism, which may lead MNCs to eventually take equity stakes in their partners, creating joint ventures (Gundelach & Hansen, 2020, p.180).

In the case of high transaction costs and high firm resources, an MNC may acquire local firms or establish local subsidiaries (Gundelach & Hansen, 2020, p.180). These options require that MNCs have "long-term internationalization experience in similar regions and continued and robust engagement by the firm

management” (Gundelach & Hansen, 2020, p.180). Following the economic liberalization of the 1990s, international acquisitions and joint ventures became more popular (Boatend & Glaister, 2003 and Dadzie & Owusu, 2015 as cited in Oguji & Owusu, 2021, p.6). *Case Studies B2 and B3* offer snapshots of joint ventures in Ethiopia and Rwanda, respectively. Between 2005 and 2014, the total value of acquisitions into Africa doubled to reach \$79 billion compared to the previous decade – a trend that experts predict will continue as MNCs from BRIC countries continue to target Africa’s growing consumer base (UNCTAD, 2015; Davies & Seigain, 2014; UNCTAD, 2017 as cited in Oguji & Owusu, 2021, p.6). The lower the cultural distance between the MNC’s home and target countries, the lower the perceived risk, and thus the more likely the firm is to choose an equity-based entry mode (Wrona & Trapeczynski, 2012, p.309). According to researchers Bhaumik and Gelb, acquisitions are popular choices in fast-growing, fast-changing markets to secure first-mover advantage (2005, p.10). Conversely, in fast-growing industries that promise long-term profitability, subsidiaries reduce agency and restructuring costs in the long run despite upfront investment (Bhaumik & Gelb, 2005, p.10; Addae & Addae, 2013, p.33).

The choice of entry mode has implications for the productivity of local firms via technology diffusion and competition (Bhaumik & Gelb, 2005, p.5). In fact, by the end of the twentieth century, FDI surpassed trade as a primary driver of economic growth in emerging markets (Bhaumik & Gelb, 2005, p.6). Technology diffusion increases with FDI (Bhaumik & Gelb, 2005, p.7). However, in most cases, MNCs’ operations in developing countries represent small segments of their overall portfolio, “usually opting for products that are...in the low-technology downstream segments of their supply chain” (Bhaumik & Gelb, 2005, p.8). Despite the importance of choice of entry mode, many MNCs make investment decisions based simply on “senior managers’ personal experiences, family ties, gut feelings, or anecdotal evidence” (Khanna, Palepu, & Sinha, 2005, p.3; Oguji & Owusu, 2021, p.7). Incomplete data on emerging markets means that MNCs’ decisions are “not necessarily based on rational, factual premises” (Wrona & Trapeczynski, 2012, p.306).

In the case of sub-Saharan Africa specifically, the jury is still out on the merits of local production compared to importing. Roughly 50% of the continent’s existing local capacity is underutilized (Chaudhuri & West, 2015, p.34). Though some researchers suggest that local production could improve access via price reductions (Gebre-Mariam, Tahir, & Gebre-Amanuel,

2016, p.65-66), others suggest that “these prices may still be relatively high compared to the paying capacity of the consumers” and would therefore produce no tangible effect (Chaudhuri & West, 2015, p.34). The efficacy of investment type is likely dependent on country, entry mode, product type, and other factors. These factors will be explored in further detail in *Case Studies B1* through *B4*.

SB1.2. Branding type

Because drugs are only granted patent protection for 20-25 years, much of which is lost during pre-market development, “developers of original medicines have sought to cover their research and development costs by maintaining high prices for their products” (Wrona & Trapeczynski, 2012, p.298; Ford, 2017, p.40). As a result, such products are often unaffordable for African patients (Ford, 2017, p.40). However, many Indian companies produce generic versions of the same drugs that are available at a fraction of the cost (Ford, 2017, p.40). These medications are especially popular among international aid organizations (Ford, 2017, p.40).

Local producers then fall into three categories: (a) indigenous firms (b) arrangements with foreign branded originators and (c) arrangements with foreign generics producers. Sub-Saharan Africa has very few indigenous firms with research and development capacity, therefore such companies are likely to use compulsory licensing to produce generics. Indian producers are leaders in the African market in both branded and generic options.

SB1.3. Production stage

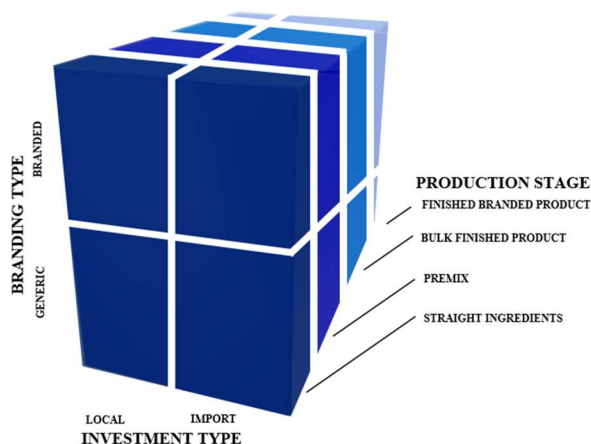
Local African producers only engage in a limited range of the value chain due to a reliance on imported raw materials (Mohamed, 2018, p.8). Almost all local producers are drug-product manufacturers, meaning they import APIs and formulate them into finished products (Conway et al., 2019, p.4; USAID, 2016, p.2). Production can thus take the following forms: (a) import APIs that are mixed and packaged by local manufacturers (b) import or produce premixes that are packaged by local manufacturers (c) import bulk finished products for local packaging and branding (d) import branded package products for local distribution (Monterrosa et al., 2018, p.1). Researcher and nutritionist Eva Monterrosa explains that “scenarios A and B require local manufacturing capacities for blending and mixing; scenario C is likely to be found in countries with lower manufacturing capabilities; and scenario D in countries with no capacity or small consumer markets” (2018, p.2). Production stage is

important for its effect on value-added taxes.

MNCs must consider the benefits of entry modes within the unique context of each new market.

Figure B1

Production Variations



Case Study B1

EPHARM, Ethiopia

In 1964, the Ethiopian Pharmaceuticals Manufacturing Share Company was established as the first pharmaceutical producer in the country (“Ethiopia: EPHARM, 2020). Then known as Ethiopian drug Manufacturing Shack (EDMSC), the company was jointly controlled by British company Smith & Nephew and the Imperial Ethiopian Government (EPHARM, n.d.). Having reported significant losses, in 1970, the government called for international bidders and signed an agreement with Israel’s TEV, the former retaining a 51% stake (EPHARM, n.d.). The company was renamed to EPHARM and began to turn a profit (EPHARM, n.d.). Though nationalized following the popular revolution of 1974, it was re-privatized in 1994 and purchased by Medtech Ethiopia in 2014 (EPHARM, n.d.). It is located in Addis Ababa and has eight production lines, including tablets, capsules, sachets, and liquids (EPHARM, n.d.).

With over 50 years of experience in the Ethiopian market and an exceptionally wide range of products, EPHARM is considered an industry leader (EPHARM, n.d.). With plans to develop another 40,000 square meter GMP-compliant factory and begin exporting to Somaliland and South Sudan, the company aims to rank among the top three African pharmaceutical companies by 2025 (EPHARM, n.d.; “Ethiopia: EPHARM,” 2020.).

However, Dr. Mohammed Nuri, Medtech’s founder and chief executive, believes there is still far to go. According to him, although “there is significant change

in the pharmaceutical industry’s landscape between now and five years ago [and] the government has now given huge attention to the sector...the country’s pharmaceutical companies barely cover 15% of local demand” (Taye, 2016). Besides, local industry is still reliant on imports for 99% of all inputs (Mulupi, 2015). Dr. Nuri also laments the “lack of access to sufficient foreign exchange” and the reliance on ground transport from the port of Djibouti, which takes almost two days (Taye, 2016; Mulupi, 2015).

Looking forward, Dr. Nuri welcomes competition: “There are some Indian companies that are coming. Branded multinationals are also on the way. There is a huge gap, so *there will be room for all of us*. Ethiopia needs more drug manufacturers” (Mulupi, 2015). Contrary to pharmaceutical giants in the West, local producers in Ethiopia are eager for price-lowering competition to help build infrastructure and achieve economies of scale. Their attitude is simultaneously collectivist and free market-based, not just at the policy level, but at the individual firm level.

Case Study B2

LABOPHAR, Rwanda

Established in 1981, the Pharmaceutical Laboratory of Rwanda used to be the sole drug manufacturer in the country (Hakizimana, 2021). In 2011, the former Procurement Agency for Medical Equipment, Drugs, and Supplies (CAMERWA) merged with LABOPHAR to create the Medical Procurement and Production Division (MPPD) of the Rwanda Biomedical Center (RBC) (Hakizimana, 2021). According to a 2018 report by the Auditor General, the medical production unit became inoperative in 2013 (Hazikimana, 2021). Because MPPD failed to perform strategic business and annual planning after the merger, its essential medicine production fell to 0% (Hazikimana, 2021). Consequently, “essential medicines that were produced by MPPD...experience recurrent stock out” and raw materials worth over RWF 350 million are either idle or expired (Hakizimana, 2021).

Before the shutdown, though, LABOPHAR was GMP-compliant and enjoyed access to skilled personnel from the neighboring National University of Rwanda (USAID, 2016, p.1). The factory produced both tablets and serums sold across Rwanda, the DRC, Burundi, and Tanzania (“LABOPHAR eyes,” 2010). In 2010, then-director Dr. Kambanda Rucweri expressed the need for government support, saying “we are currently facing the problem of budgetary constraints because we have to largely depend on the sales” (“LABOPHAR eyes,” 2010). Struggling to gain market share both locally and

internationally, LABOPHAR was directly engaged in creating and educating its market, advocating for the safety and usage of local drugs over imports (“LABOPHAR eyes,” 2010).

Frustration over LABOPHAR’s failure is expressed at the national level by members of parliament, who support local manufacturing as good for the economy. According to MP Jeanne d’Arc Uwimanimpaye, the government’s role is to invest in those areas that private investors are reluctant to due to high barriers to entry (Hakizimana, 2021). In the case of pharmaceuticals, the draw is even greater, as the industry is highly profitable (Hakizimana, 2021). Similarly, MP Christine Bakundufite complained “why can’t we back LABOPHAR instead of just criticizing it” (Hakizimana, 2021).

In 2019, RBC Director-General Dr. Sabin Nsanzimana told lawmakers that despite talks with over ten investors scouted for overtaking LABOPHAR, private sector interest was limited due to the lab’s old equipment, small land, and non-GMP compliant facilities (Hakizimana, 2021). Other issues include poor asset and equipment management and embezzlement, which caused government losses of over RWF 5.8 billion between 2013 and 2018 (Sabiiti, 2020).

In response to shortages, the government is now in the process of introducing the Rwanda Medical Supply (RMS) to replace MPPD, which will be authorized to import directly from international manufacturers (Uwizeyimana et al., 2021, p.3).

Case Study B3

Cadila Pharmaceuticals, Ethiopia

In 2007, owning 57% and 43% respectively, Cadila Pharmaceuticals of India partnered with Almeta Impex PLC of Ethiopia to create Cadila Pharmaceuticals Ethiopia PLC (CPEL) (Gebre-Mariam, Tahir, and Gebre-Amanuel, 2016, p.68). The venture was Cadila’s first overseas formulation manufacturing facility and was largely motivated by potential market size (“Cadila opens,” 2007; Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.68). The \$10 million plan imported all machinery and raw materials from India, and now has capacity to manufacture 390 million tablets, 165 million capsules, and 1.44 million liters of liquid annually in its 10,6000 square meter campus (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.68; “Cadila pharma’s,” 2011). In 2011, the company earned a GMP certificate (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.68).

The joint venture was celebrated by Ethiopian Minister of Trade and Industry Girma Birru as a “milestone in the relationship between India and Ethiopia” (“Cadila opens,” 2007). Executive vice president of international business at Cadila Pharmaceuticals Mahidhwaj Sisodia explained the strategic partnership:

While starting out, we had to deploy manpower from India.... But gradually we started building the local skills. We have empowered local leadership and people to take over and lead operations. The secret to our acceptance was that we always considered ourselves a local company by adapting their culture and values (Ruchika, 2020).

CEPL’s joint venture strategy is supported by USAID, which describes such entry modes as “catalysts for the development of the pharmaceutical industry in Africa” (2016, p.2). The transfer of skills and technology is critical to the development of local capacity (USAID, 2016, p.2). For the foreign partner, joint ventures offer a “localization of knowledge,” which is particularly important given that the “effectiveness and nature of formal and informal institutions” are both critically important and complex in developing countries (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.66; North, 1990; Chen et al., 2017; Meyer et al., 2009; & Peng, 2014 as cited in Gundelach & Hansen, 2020, p.178).

Case Study B4

CSM Global Pharma

In 2011, India’s Cadila Pharmaceutical Ltd planned a joint venture with American Holtzman Group to be named CSM Global Pharma (“\$65M to be invested,” 2011). The new facility in Kigali would cost \$65 million and have capacity for solids, liquids, biologicals, and even APIs (Das, 2013). The plan was also celebrated for its expected job creation and technology diffusion (Das, 2013; “\$65M to be invested,” 2011). With around 30% of imports into Rwanda being counterfeit, CSM was touted as a path to import independence by producing high quality drugs at competitive prices (“\$65M to be invested,” 2011).

However, after 2014, there is no available information on the company, suggesting its formation was never completed.

Appendix C

Figure C1

Factors Determining Local Production Capacity

HIGH PRIORITY	Economies of Scale
MEDIUM PRIORITY	Regulatory Environment
	Input Materials
	Capital Investment and Access to Affordable Finance
LOW PRIORITY	Skilled Personnel
	Infrastructure
	Access to Technology

Source: Mohamed, 2018, p.26. Supported by studies conducted by Chaudhuri & West, the International Trade Association, McKinsey & Company, and others.

Supplement C1. Ethiopia Additional Information

SC1.1. Historical background

Ethiopia is located in East Africa and borders Djibouti, Kenya, Somalia, South Sudan, and Sudan. Though the Ethiopia-Somalia border is largely undefined, the country's size is generally accepted to be just less than twice the size of Texas (CIA, 2021a). *Figure C2* provides a map. Ethiopia is the "oldest independent country in Africa and one of the oldest in the world," having avoided colonization with the exception of a brief Italian occupation from 1936 through 1941 (CIA, 2021a).

In 1974, Ethiopia became a socialist state under a military junta, the Derg (CIA, 2021a). The regime was overthrown in 1991 and replaced by a federal parliamentary republic, which adopted its constitution in 1994 (CIA, 2021a). The country is divided into "nine ethnically-based regional states and two self-governing administrations" and uses a civil law system (CIA, 2021a).

In 2012, Prime Minister Zenawi died in office and was replaced by Deputy Prime Minister Desalegn – "the first peaceful transition of power in decades" (CIA, 2021a). In 2018, following several years of popular protest, Desalegn resigned and Abiy Ahmed took office (CIA, 2021a).

SC1.2. Economies of scale

Local producers require large markets to achieve economies of scale, as manufacturing has high fixed costs in machinery, qualified personnel, and insurance, as well as other inputs. Ethiopia's sheer size – a population of over 100 million and the second most

populous in Africa – makes it a large target market for medicines generally (CIA, 2021a). According to Anteneh Senbeta, deputy commissioner for corporate affairs at the Ethiopian Investment Commission, Ethiopians spent \$700 million annually on drugs as of 2018 – a value expected to grow dramatically (Gebre, 2018). A 2017 study by Misganaw et al. in Ethiopia found that between 1990 and 2015, "non-communicable diseases were the leading causes of age-standardized mortality rates," reflecting the shift towards NCDs (Misganaw et al., 2017, p.1). For anemia specifically, despite a more than 50% reduction in IDA over the study period, as of 2016, 57% of Ethiopian children under five years of age "suffered from some degree of anemia (haemoglobin levels below 11 g/dl)" (Misganaw et al., 2017, p.1; Central Statistical Agency [CSA] & ICF, 2016, p.195). 24% of women and 15% of men were also found to be anemic (CSA & ICF, 2016, p.199).

But many other factors combine to make an anemic individual a haematinic consumer. Ethiopia has a low per capita GDP of just \$2,221 as of 2019, roughly one-third of India's (CIA, 2021a; CIA, 2021c). This makes consumers particularly price sensitive. Moreover, anemic individuals may not know their health status, as physician density in Ethiopia is just 0.08 physicians per 1,000 population (CIA, 2021a).

A 2015 simulation study conducted by researchers Chaudhuri and West explored the feasibility of local production in Ghana given cost constraints. It concludes that local manufacturing is feasible only if large markets are ensured through government cooperation (Chaudhuri & West, 2015, p.35). Though not specific to Ethiopia, the report's principles still apply.

According to the study, "if the international suppliers lose markets because of local production, they can and do retaliate by reducing their prices" (Chaudhuri & West, 2015, p.34). Governments buy drugs in large quantities through competitive bidding processes, driving down prices that are annually reported in the WHO's International Drug Price Indicator Guide (Chaudhuri & West, 2015, p.24). These prices act as international reference prices and are considered the cheapest at which medicines can be bought or sold (Chaudhuri & West, 2015, p.34). If local producers charge these prices, they become competitive with international producers and reduce prices for consumers (Chaudhuri & West, 2015, p.35). So long as the international reference price is higher than the cost of production, local manufacturing is possible if the necessary market is secured (Chaudhuri & West, 2015, p.35). In other words, local manufacturers will likely have lower profit margins due to higher input costs, but

government intervention can offset this loss with higher volume via import restrictions, public procurement regulations, or reimbursement under national insurance (Chaudhuri & West, 2015, p.36-37).

Though it is unlikely that international suppliers would offer prices below the international reference prices, even if they did, local production does not become unviable unless “the imported price is higher than the local average variable cost per unit,” which is unlikely (Chaudhuri & West, 2015, p.35-36). The size of the market is the most crucial determinant of feasibility.

To some degree Ethiopia has already acknowledged this. According to the International Trade Administration, the Ethiopian Pharmaceutical Supply Agency solicits imports through tender announcements “made accessible to all interested potential bidders, regardless of the nationality of the supplier or origin of the products” (2020a). Drugs are also imported via tender by the Ministry of Health, PHARMID, non-governmental organizations, and private importers (Embassy of the Federal Democratic Republic of Ethiopia [EFDRE], 2015, p.2).

Though some concerns have been raised regarding the lack of transparency in the bid evaluation processes, this tender system generally represents an attempt at non-discriminatory procurement (ITA, 2020a). This process lowers drugs prices compared to monopolies or long-term contracts. However, advocates of local production argue that, contrary to the free-market economics popularized in Africa in the 1990s, the government should take sides - an initial non-competitive decision to favor local production will actually enhance long-term competition at home by opening markets for domestic manufacturing.

At the front end of the supply chain, Ethiopia has implemented incentives for local production including tax breaks and customs exemptions (“Local pharma,” n.d.). Between 2016 and 2018 alone, foreign companies invested \$213 million into the industry “lured by government offers to facilitate exports and allow companies to repatriate profits” (Gebre, 2018). For India specifically, one such incentive is the 2011 DTAA with reduced rates for dividends, interest, royalties, and fees for technical services.

Other government interventions include incentives under the Industrial Development Strategy, which identifies the private sector as the “engine” of the manufacturing sector’s growth (EFDRE, 2015, p.1). The pharmaceutical industry is given priority as a sub-sector, with incentives to produce “products that substitute for imported products and also supply export markets”

(EFDRE, 2015, p.1). Local manufacturing helps correct the country’s trade deficit by a) reducing imports and b) potentially increasing exports. Production registration time has been reduced to a month for local manufacturers, and if the firm exports 50% of their products, they are also eligible for an income tax exemption for five years (“Local pharma,” n.d.). Ethiopia’s membership in the Common Market for Eastern and Southern Africa (COMESA) offers preferential tariffs among 19 member countries, and proximity to the Middle East also offers potential trading partners (EFDRE, 2015, p.4). In 2016, Ethiopia joined the African Trade Insurance Agency, which covers political risk for international investors and thus further supports FDI (ITA, 2020a).

Besides sufficient medical demand, to reach economies of scale, local manufacturing requires government assistance. This cooperation appears to have started with GOE investment incentives.

SCI.3. Regulatory environment

Ethiopia’s planned economy features significant government involvement throughout the supply chain. Under the 1994 constitution, the state owns all land and leases to tenants, resulting in corrupt and poorly regulated property rights, especially in urban areas like Addis Ababa (CIA, 2021a). State ownership of key industries, including telecommunications, banking, and energy further constrain market growth (CIA, 2021a; ITA, 2020a). In the 1980s and 1990s, following global trends of neoliberalism, Ethiopia began liberalizing through privatization (Rodrik, 2000, p.4). By the early 2000s, however, the “institutional underpinnings of market economies” were revealed through the foreclosure of four pharmaceutical manufacturers unable to compete against unregulated, substandard drugs (Rodrik, 2000, p.4; Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.67). The Ethiopian government thus began a period of reform to secure property rights, reduce fraud and anti-competitive behavior, and enforce corruption legislation (Rodrik, 2000, p.4). In the absence of a pan-African regulatory body, individual efforts by Ethiopian agencies have resulted in a fragmented and highly complex web of agencies, initiatives, and law (Lartey et al., 2018, p.6). For this reason, foreign producers often seek local partnerships to tap into regulatory expertise (Lartey et al., 2018, p.6).

SCI.3.1. Players and programs

Ethiopian regulators cover areas such as drug registration, taxes, and investment incentives – all of which affect FDI decisions. In 2009, the African

Medicines Regulatory Harmonization (AMRH) was launched as part of the Pharmaceutical Manufacturing Plan for Africa to standardize the capacities of national medical regulatory authorities (Lartey et al., 2018, p.6; Kaufman et al., 2021). Among these capacities were drug registration, variation of which often prevents manufacturers from registering products outside their countries of operation (Lartey et al., 2018, p.5-6). This limits local manufacturing and therefore not only acts as a “barrier to access but also constrains market size” (Lartey et al., 2018, p.5). In 2015, the AMRH was transitioned into a continental regulatory authority called the African Medicines Agency (Lartey et al., 2018, p.7).

The government’s commitment to “reducing delays in product registration, ferreting out counterfeit drugs, and pushing manufacturers to meet standards required for exports” is also seen in reforms of the Food, Medicine, and Healthcare Administration and Control Authority (FMHACA), the Ethiopian Food and Drug Administration (EFDA), and the Ethiopian Pharmaceutical Supply Agency (EPSA) (Conway et al., 2019, p.7; ITA, 2020a). FMHACA and EFDA share “regulatory oversight for the registration, importation, and quality of medicines,” while “EPSA is the public procurement agency responsible for purchasing pharmaceuticals” (ITA, 2020a). FMHACA is also offers local investment incentives, promising proprietary registration for locally-manufactured products (EFDRE, 2015, p.8).

Other local investment incentives include the Pharmaceutical Fund and Supply Agency (PFSA), which offers “30% advance payment for the purchase of [local] products won through national bidding and 25% price preference when local manufacturers participate in international bids” (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.72). To attract FDI, the Development Bank of Ethiopia offers up to 70% of the investment capital for new pharmaceutical investments, 7.5% interest rates with long-term repayment horizons, customs duty privileges for capital goods, and tax holiday privileges, among other incentives (EIC, 2014 as cited in Gebre-Mariam, Tahir, Gebre-Amanuel, 2016, p.78). GOE’s national policies have “been historically encapsulated in the...Growth and Transformation Plan (GTP),” which “lays out a plan for dramatic structural transformation, shifting from an agrarian economy to one more geared towards manufacturing and services” (ITA, 2020a). At the international level, the formation of the Federation of African Pharmaceutical Manufacturers Associations (FAPMA) in 2013 represented regional coordination on industry growth and contributed to the development of the

Pharmaceutical Manufacturing Plan for Africa – Business Plan (PMPA-BP), a WHO-sponsored development framework (Lartey et al., 2018, p.7-8).

While the coordination failures of the late 1990s “make it clear that strategic government interventions may often be required to get out of low-level traps and elicit desirable private investment responses,” the overlapping authority of private and public local, national, regional, and international players frustrates efforts at cohesive policy reform (Rodrik, 2000, p.7). This is seen again in Ethiopian tax law. The East African Community removed duties on finished pharmaceutical products around 2010, but import duties have remained on raw materials, increasing prices for local producers (Ford, 2017, p.41). Local production requires the import of raw materials and packaging, since Ethiopian capacity only currently exists at the secondary level (Lartey et al., 2018, p.5). To recover local producers lost market share, the government has implemented a wide range of other investment incentives, including preferential treatment in government procurement and DTAAAs with key investors (Ford, 2017, p.41). While perhaps a step in the right direction, the incentives remain piecemeal.

SC1.3.2. Good manufacturing practice (GMP)

The dearth of coordination is particularly evident in efforts to attain international GMP compliance. According to law firm Gowling WLG, specialists in African healthcare, GMP compliance “enables domestically manufactured pharmaceuticals to be traded in confidence between countries,” but implementation “requires the alignment of domestic policies across various government departments such as health, commerce, trade, and industry” (Ford, 2017, p.41). GMP standards cover all components of the production process from starting materials to labor (Chaudhuri & West, 2015, p.25). Most African countries, Ethiopia included, “lack the facilities, equipment, analytical instrumentation, and the human capital...to attain and maintain compliance” (Lartey et al., 2018, p.4). Compliance is also costly – GMP equipment is often custom designed and imported with long lead times and upfront payments (Lartey et al., 2018, p.8). But non-compliance is also costly – local manufacturers who do not meet GMP guidelines have limited export markets and suffer from weaker reputation.

SC1.3.3. Recent changes

Despite continued challenges with bureaucracy and customs clearance times, according to McKinsey researchers Conway et al., “Ethiopia is investing ahead of the curve in regulatory capacity” (ITA, 2020a; Conway et al., 2019, p.7). With a regulatory budget of

\$6.6 million, Ethiopia enjoys a higher regulatory budget to market value ratio than Brazil, Russia, and Turkey (Conway et al., 2019, p.7). In 2019, Prime Minister Ahmed furthered liberalizing reform by launching the Home Grown Economic Reform Agenda, which encourages FDI (ITA, 2020a). Ahmed has also formed an interministerial committee to improve the country's Ease of Doing Business ranking (ITA, 2020a). Ethiopia could perhaps learn from South Africa, whose Medicines and Related Substances Control Amendment Act requires pharmacists to offer generic alternatives to patients when available, representing government support of the local generic market and ultimately lowering prices for consumers (NAPM, 2009, p.138-139). Since the Keynesianism of the 1990s, Ethiopia has "come to a better understanding of the reality that capitalist economies are not necessarily self-stabilizing," and that a "mix of state and market, laissez faire and intervention" is preferential for healthy domestic competition (Rodrik, 2000, p.7, 10).

SCI.4. Input materials

As previously mentioned, pharmaceutical manufacturing in Ethiopia is currently limited to secondary stages, requiring the import of 95% of APIs and raw packaging materials (EFDRE, 2015, p.3; Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.73). These materials are the primarily variable costs of production, making Ethiopian industry sensitive to international prices (Chaudhuri & West, 2015, p.27). Because African manufacturers are relatively small, "input materials are purchased in...quantities...at times too small to attract suppliers, and as a result manufacturers have no power to negotiate," resulting in higher prices (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.70). As Chaudhuri & West's simulation study explains, foreign reliance disadvantages African producers even if international competitors purchase APIs from the same source because of higher freight, insurance and working capital costs (2015, p.31). African manufacturers must hold greater inventories for much the same reasons – creating additional costs in storage, insurance, and interest (Chaudhuri & West, 2015, p.31).

Other input costs include machinery and technical assistance, which, because nearly always imported, represent significant barriers to entry for local firms given the lack of financing (to be discussed later) (Chaudhuri & West, 2015, p.31). Electricity costs are also high in Ethiopia, as "demand continues to outpace supply" and "transmission lines and distribution facilities are inadequate" (ITA, 2020a). Though Prime Minister Ahmed has supported projects to increase

hydropower capacity, improvement is relatively slow due to state ownership and subsequent bureaucracy of the power distribution industry (CIA, 2021a). Input, inventory, and other variable costs continue to be major barriers to profitable production.

SCI.5. Capital investment and access to affordable finance

Ethiopia suffers from an acute foreign exchange shortage resulting from excessive imports (ITA, 2020a). According to the International Trade Administration, the shortage limits "timely procurement of equipment, supplies, and pharmaceuticals" and may also lead to payment delays and exposure to price fluctuations (2020a; Gebre-Mariam, Tahir, Gebre-Amanuel, 2016, p.83). In an attempt to improve the trade imbalance, in 2017, the National Bank of Ethiopia devalued the birr by 15% relative to the US dollar (CIA, 2021a; ITA, 2020a). Experts are divided on the projected effect of local manufacturing – some argue that local production could improve the deficit by reducing the need for imports and, eventually, contributing to exports. Others, such as researchers Conway et al. of McKinsey & Company suggest that any improvements would amount to "less than 5% of Ethiopia's projected foreign currency needs – not including the additional capital investments needed to build industrial parks and upgrade national regulators" (2019, p.8).

The Ethiopian birr also suffers from high inflation, which has ranged from a high of 44% to a low of 6.63% over the 2008-2019 period (Pletcher, 2020). For MNCs looking to expand into Ethiopia, this is particularly unfavorable, as profits will likely be converted to foreign currency. Though 18 financial institutions and insurance companies exist in Ethiopia, only a fraction of surveyed Ethiopian firms obtained loans from domestic banks, citing "impossible" approval conditions (Hailu, 2017, p.31, 37).

Ethiopia remains reliant on non-governmental organizations and international aid agencies to provide essential medicines, most of which are purchased abroad (Owoeye, 2014, p.215). The United Nations Economic Commission for Africa (UNECA) awards over \$200 million in contracts annually using a centralized procurement system shared with the other 21 UN agencies located in Addis Ababa (ITA, 2020a). In 2016, the Fund for African Pharmaceutical Development (FAP-D) was created by the African Union to "provide affordable financing to the industry in the form of low interest rate[s]" and long-term support (Lartey et al., 2018, p.9). All African Union member states are required to contribute funds (Lartey et al., 2018, p.9).

The program was created in the image of the Indian Credit Linked Capital Subsidy Scheme (CLCSS) that “enables small- and medium-sized pharmaceutical companies to access low interest rate, long-term government funds for upgrading, product promotion, and marketing” (Lartey et al., 2018, p.9). The CLCSS is credited with positioning the Indian pharmaceutical sector as the third leading industry globally (Lartey et al., 2018, p.9).

Over the past several decades, Africa has received trillions of dollars in developmental aid despite evidence that such funding has long-term “negative effects on private investment in developing countries” (Moyo, 2009; Herzer & Grimm, 2012; Selaya & Sunesen, 2012 as cited in Addae & Addae, 2013, p.32-33). By contrast, FDI is believed to be pathway to decreased dependence on foreign aid (Moto, 2009 as cited in Addae & Addae, 2013, p.33).

SCI.6. Other factors

Among the factors necessary for local pharmaceutical manufacturing, labor, infrastructure, and technology are among the easiest to build, making them the lowest priority consideration for market entrants (Gebre, 2018).

SCI.6.1. Skilled personnel

Despite strong economic growth of an annual average of 10.3% in between 2006 and 2016, “Ethiopia remains one of the world’s poorest countries and low wages remain a big draw for investors” (Gebre, 2018). Even by Chinese standards, Ethiopian factory wages of \$75 per month are quite low (Gebre, 2018). Talent scarcity is particularly pronounced for those with industrial or managerial skills – only 7% of Africans hold tertiary degrees (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.70; Holt et al., 2015, p.7). Ethiopia’s school life expectancy is just nine years, and only 7.4% of the labor force works in industry (CIA, 2021a). *Figure C3* shows the standard world map, while *Figure C4* shows the same map adjusted for working pharmacists, highlighting scarcity in Africa.

Wage costs are also a concern for local manufacturers attempting to maintain cost competitiveness. In emerging markets, because “the market for casual labor is not as developed,” casual employees (in effect) become permanent employees and are therefore a fixed cost (Chaudhuri & West, 2015, p.32). Low wages are offset by low productivity due to limited technical skills (Chaudhuri & West, 2015, p.32). Though average labor costs can be reduced through

larger batch sizes, only larger firms can afford to produce at such volume (Chaudhuri & West, 2015, p.32).

Although supporters of local production tout manufacturing as an opportunity for employment, critics suggest that any gains would be modest due to trends toward automation (Conway et al., 2019, p.8). Estimations of job creation are as low as a few thousand jobs, even including upstream and downstream effects (Conway et al., 2019, p.8). Lack of skilled personnel contributes to the leanness of new plants, but it also contributes to the underutilization of existing facilities (Conway et al., 2019, p.8; Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.67)

SCI.6.2. Infrastructure and capacity utilization

Ethiopia’s population is largely rural, and a central mountain range creates infrastructure challenges for road construction (CIA, 2021a). As of 2017, Ethiopia has but 17 airports with paved runways and just one registered air carrier (CIA, 2021a). It also has 659 kilometers of railway (2017) and 120,000 kilometers of roads (2018) (CIA, 2021a). By contrast, France, which is half Ethiopia’s size with 40 million less citizens, has 294 airports with paved runways (2017), 19 registered air carriers (2020), over 29,000 kilometers of railway (2014), and over 1 million kilometers of roads (2011) (CIA, 2021b). Ethiopia is landlocked and is reliant on the ports of Djibouti and Somalia for ocean freight (CIA, 2021a).

The lack of transportation infrastructure creates long lead times and generates higher communication, inventory, and insurance costs (Holt et al., 2015, p.9). End-to-end logistics providers, which “allow manufacturers to reduce costs,” are limited (Khanna, Pelepu, & Sinha, 2005, p.1). According to a study by Bangalee & Suleman, the logistics fees of generic medicines represent a higher percentage of the single exit price (at which a pharmacy buys the drug from its suppliers) than for their originator branded counterparts (2015, p.9; NAPM, 2009, p.141). Based on a logistics fee cap experiment in South Africa, branded manufacturers were suspected of offering distributors and wholesalers higher logistics fees as incentives for selection for distribution, therefore disrupting the competitive environment and driving up logistics costs across the industry (Bangalee & Suleman, 2015, p.2, 9).

Capacity utilization is also an issue. During the period 1995 to 2004, pharmaceutical manufacturers in Ethiopia operated at only 50% of installed capacity (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.67). This figure improved from 2005 to 2014, reaching 79% in 2013 and reflecting a growing market for local

production (Gebre-Mariam, Tahir, & Gebre-Amanuel, 2016, p.70). Low utilization is inefficient and increases production cost per unit.

SCI.6.3. Technology

In recent years, some improvements have been made to logistics in Ethiopia with the introduction of technology platforms under the Pharmaceutical Supply Agency (ITA, 2020a). Vitas supports logistics management, warehouse management, and inventory control to improve purchasing decisions (ITA, 2020a). Dagu is similar and supports logistics management and inventory control at 700 service delivery points (ITA, 2020a). Generally speaking, however, the availability of reliable data on both supply chains and customer preferences in sub-Saharan Africa is lacking (Lartey et al., 2018, p.5; Kaufman et al., 2021; Khanna, Palepu, & Sinha, 2005, p.1; Kaine & Nwokike, 2020).

SCI.7. Ethiopian-Indian relations

Ethiopian-India relations have enjoyed roughly 2000 years of trade partnership (“India-Ethiopia relations,” 2017, p.1). Cooperation on political, economic, and developmental projects generates benefits for both parties.

Diplomatic relations were formally established between the modern countries in 1950 (Purushothaman, 2018). Although dealings have traditionally been friendly, regime changes in Ethiopia have caused some interruptions in cooperation (“India-Ethiopia relations,” 2017, p.1). Under the communist Derg regime, for example, many Indian businessmen and teachers left Ethiopia (“India-Ethiopia relations,” 2017, p.1). Following the democratic and liberalizing reform of the early 1990s, Indian investment in Ethiopia rose significantly, especially in infrastructure (“India-Ethiopia relations,” 2017, p.1, 3).

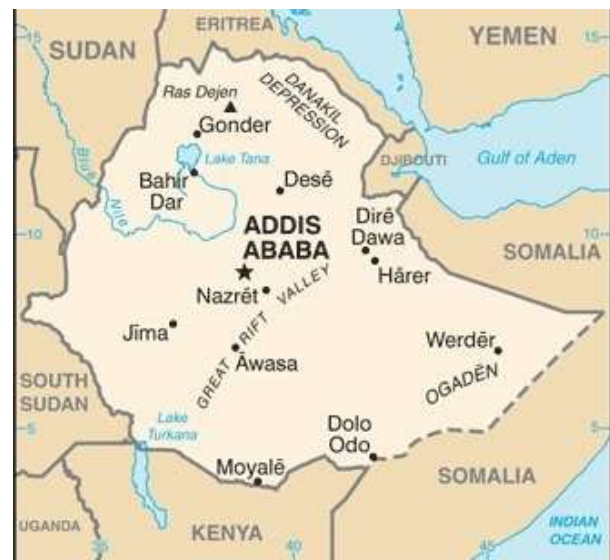
Ethiopia became largest recipient of India’s Lines of Credit (LOCs) in Africa with a 2015 commitment of \$1 billion by New Delhi (Purushothaman, 2018). According to the Indian Ministry of External Affairs, as of 2016, bilateral trade was valued at “\$1.37 billion, of which India’s exports to Ethiopia were \$1.3 billion” (2017, p.4). Of this, 13% was attributed to drugs and pharmaceuticals (“India-Ethiopia relations,” 2017, p.4). India is the country’s third largest importer behind China and the United States, contributing 7.7% of all Ethiopian imports (“India-Ethiopia relations,” 2017, p.4).

India is a leading investor with over “540 Indian companies in Ethiopia with licensed investment of over US \$4 billion of which about US \$2 billion is estimated to be on the ground” (“India-Ethiopia relation,” 2017,

p.4). Primary investment sectors include pharmaceuticals, manufacturing, and healthcare (“India-Ethiopia relations,” 2017, p.4). Joint venture Cadila Pharmaceuticals PLC is one such investment example (see: *Case Study B3*) (“India-Ethiopia commercial,” n.d.; EFDRE, 2015, p.2).

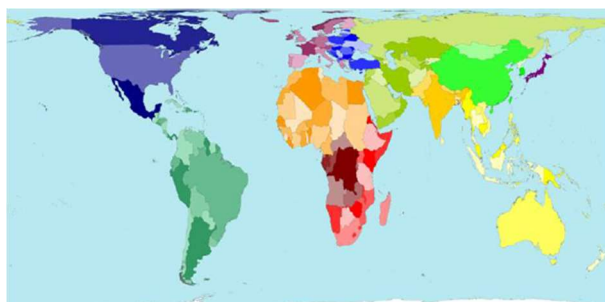
The Indian Technical and Economic Cooperation (ITEC) program supports education and capacity building in Ethiopia by providing training for Ethiopian students at Indian universities (Purushothaman, 2018). Between 2007/2008 and 2016/2017, the number of ITEC slots for Ethiopian students has been expanded tenfold (Purushothaman, 2018). Other programs, including scholarships from the Indian Council of Cultural Relations, agreements on Cooperation in Science and Technology, and investment in agricultural, textile, and energy projects have “helped India build immense goodwill among both the civilians and the defense personnel” of Ethiopia (“India-Ethiopia relations,” 2017, p.8-9; ITA, 2020a; Purushothaman, 2018). Diplomatic relations are currently close, as Ethiopia Airlines currently offers daily flights to Mumbai and New Delhi and Indian presence is particularly pronounced among Ethiopian higher education institutions (“India-Ethiopia relations,” 2017, p.10).

Figure C2
Map of Ethiopia



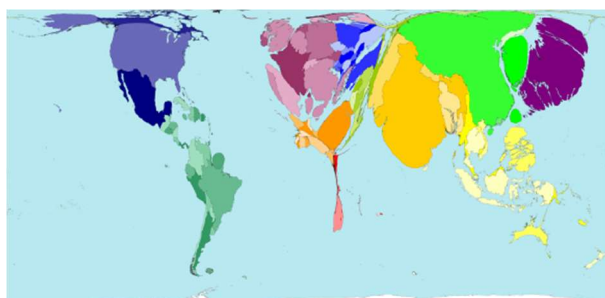
Source: CIA, 2021a

Figure C3
Standard World Map



Source: Mohamed, 2018, p.27

Figure C4
World Map Adjusted for Pharmacists Working



Source: Mohamed, 2018, p.31

Supplement C2: Rwanda Additional Information

SC2.1. Historical background

Rwanda is located in Central East Africa and borders Uganda, Tanzania, Burundi, and the Democratic Republic of the Congo (DRC). With a geographic area smaller than that of Maryland with over 12 million citizens, Rwanda is one of the most densely populated countries in Africa (CIA, 2021d). *Figure C5* provides a map.

Rwanda's colonial and post-colonial history is rather tumultuous, having been conquered by the Germans in 1898 and then captured in 1916 by Belgium (CIA, 2021d). Under both colonial regimes, the Tutsi ethnic group was favored (CIA, 2021d). Ethnic tensions came to a head in 1959, three years before independence from Belgium, when the majority ethnic group, the Hutus, organized a coup against the Tutsi king. (CIA, 2021d). Over the next several years, thousands of Tutsis were killed or exiled, the children of the latter group ultimately forming the Rwandan Patriotic Front (RPF), a rebel group that would start a civil war in 1990 (CIA, 2021d). The civil war culminated in a 1994 state-orchestrated genocide (CIA, 2021d).

Rwanda is now a presidential republic divided into four provinces and one city (CIA, 2021d). It's first post-genocide presidential and legislative elections were held in 2003, the same year as the signing of its new constitution (CIA, 2021d). Rwanda uses a mixed legal system of German- and Belgian-inspired civil law and customary law (CIA, 2021d). Its current heads of state are President Paul Kagame and Prime Minister Edouard Ngirente (CIA, 2021d).

SC2.2. Pharmaceutical industry structure

The Rwandan pharmaceutical market can be subdivided as follows: (a) government-operated manufacturers and (b) private importers (USAID, 2016, p.1). As of 2018, there was no local production by MNCs (US Department of Commerce [USDOC], 2018). According to a 2018 audit, the Pharmaceutical Laboratory of Rwanda's (LABOPHAR) production stopped in 2013 (Hakizimana, 2021). Indian pharmaceuticals dominate the market through imports, reaching Rwandan consumers through wholesalers who jack up prices and increase uncertainty (Uwizeyimana et al., 2021, p.3).

The Medical Procurement and Production Division (MPPD) of the Rwanda Biomedical Center (RBC) currently "performs the procurement, storage, and distribution of health commodities to public health institutions" and is considered to be the central medical store (Uwizeyimana et al., 2021, p.3). However, existing regulations prevent MPPD from "importing pharmaceuticals directly from international manufacturers" (Uwizeyimana et al., 2021, p.3). Consequently, MPPD use intermediate suppliers who import the drugs themselves, adding an additional link in the supply chain and increasing prices (Uwizeyimana et al., 2021, p.3).

In the private sector, wholesale pharmaceutical companies import directly from international manufacturers and sell to community pharmacies, private health clinics, and hospitals (Uwizeyimana et al., 2021, p.2). In both cases, India is the major supplier (USDOC, 2018).

SC2.3. Local production capacity

Like Ethiopia, Rwanda's business environment offers a mixed bag for potential investors. In both countries, if one acknowledges the structural cost barriers, the key to pharmaceutical manufacturing feasibility is volume. Market access must be secured by government intervention, at least in beginning stages of industry development.

The Rwandan government, much like Ethiopia, has

implemented some measures to this effect. Rwanda's growing middle class is a selling-point for potential investors. Even more significant is the country's membership in the East African Community (EAC), a customs union of over 177 million potential customers (ITA, 2020b). Recognizing this appeal, since the 1990s, Rwanda has streamlined business registration to now take just one day (USDOC, 2018).

However, instead of acting as the starting point for investment, Rwanda has used the EAC as a constraint. By favoring the Community in import duties, hiring, and visa registration, Rwanda disadvantages European, Indian, and Chinese investment (ITA, 2020b). Other limitations include "delays in government payments for services or goods delivered, changes in MOU conditions during contract negotiations, and/or additional tax assessments" as well as "inconsistent application of tax incentives and import duties" (ITA, 2020b). Like Ethiopia, despite efforts to improve local production, regulation remains complex and inadequate (USAID, 2016, p.1).

In terms of input materials, Rwanda is much like Ethiopia in that it is fully reliant on imports of raw pharmaceutical materials like APIs, excipients, and even machinery spare parts (USAID, 2016, p.3). For both countries, India is among the main import sources ("India-Rwanda relations," 2013, p.4). The two countries also share high electricity costs, though Rwanda's rates exceed those of "other East African countries and rank in the top ten most expensive tariffs in sub-Saharan Africa" (ITA, 2020b; USAID, 2016, p.1). Both countries being landlocked, all trade must be conducted by road or air despite relatively limited infrastructure, which increases lead times and transportation costs (ITA 2020b, CIA, 2021d). These expenses increase the total cost of production (USAID, 2016, p.1).

As in Ethiopia, access to financing in Rwanda is challenging, with "high interest rates and limited local capital markets" (ITA, 2020b). Rwanda also shares Ethiopia's lack of skilled labor (ITA, 2020b).

SC2.4. Rwandan-Indian relations

Indian-Rwandan relations are positive and have improved since their official recognition in 1999 ("India-Rwanda relations," 2013, p.1). India's interest in Rwanda increased dramatically following the latter's membership in regional economic communities such as the EAC ("India-Rwanda relations," 2013, p.1). Like Ethiopia, Rwanda is the recipient of an \$80 billion EXIM Bank Line of Credit for a hydroelectric power project

expected to improve generation capacity by nearly 50% ("India-Rwanda relations," 2013, p.3). Also like Ethiopia, Rwanda enjoys Indian support of education with ITEC slots and Indian professors at Rwandan universities ("India-Rwanda relations," 2013, p.3-4). Though Rwanda does not currently have a DTAA with India, diplomatic and trading relations remain close.

Figure C5
Map of Rwanda



Source: CIA, 2021d

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