PS&D 28
4TH QUARTER 2017

Private Sector & Development

PROPARCO'S MAGAZINE

IMPROVING THE QUALITY AND ACCESSIBILITY OF AFRICAN MEDICINE

Medicine - Pharmaceutical industry
Accessibility - Quality - Africa

PROPARCO
GROUPE AGENCE FRANÇAISE DE DÉVELOPPEMENT

PRIVATE SECTOR & DEVELOPMENT
is published by Proparco,
Agence Française
de Développement Group,
share capital of EUR 693,079,200,
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Editorial offices
(:?!;)DOUBLEPONCTUATION,
www.doubleponctuation.com,
Neil O'Brien/Nollez Ink

Printing on recycled paper
Pure Impression

ISSN 2103 3315
Legal deposit at publication
23 June 2009

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The private sector and pharmaceutical industry in Africa

Marie-Paule Kieny

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Providing access to quality medicines still poses a number of challenges in Africa. Distribution channels are often fragmented, with a large number of intermediaries or parallel channels, which often fuel counterfeiting – a real public health issue. For example, it is estimated that some 60% of medicines bought in the Gulf of Guinea are classified as "SF" (substandard and falsified) by the World Health Organization (WHO). Furthermore, the problem does not only affect Africa as 10% of all the medicines in circulation around the world could be "SF".

As for local production, it is still struggling to find a niche in an African pharmaceutical market which is 70% sourced from foreign imports. It is also marked by difficulties to access raw materials, especially active ingredients, and major logistical constraints (maintaining a continuous cold chain, complexity of customs clearance procedures, uncertain delivery times, etc.). For example, in Sub-Saharan Africa, apart from in South Africa and Tanzania, it is difficult or even impossible to find active ingredient production units. Other barriers to the development of private players in the drugs economy on the Continent include access to financing, the implementation of effective industrial tools, the lack of regulatory harmonization between countries and the availability of highly qualified personnel.

Yet the increasing incidence of chronic diseases (cancer, diabetes, lung infections, heart disease, etc.), the demographic transitions underway, the increasing number of generic drugs produced, the promise of universal coverage and the emergence of middle classes with a purchasing power that they are partly willing to dedicate to their health, are all factors which increase demand for medicines in Africa. Indeed, according to estimates, projected expenditure on pharmaceutical products is expected to reach between USD 40bn and USD 45bn a year in Africa by 2020, against USD 14.5bn in 2010.

Synergies between public and private players are essential in addressing the expected development of the pharmaceutical industry sector in Africa in the coming years. As State budget resources are already low, private or non-profit players are being increasingly called upon by public authorities as an alternative to sometimes deficient drug supply and distribution systems.

Four main criteria can be used to define the issues of access to medicines in Africa, which it is essential for players from both the public and private sectors to provide a response to: making medicines available that are consistent with the needs of populations and in sufficient quantity; making prices affordable for patients and health systems; ensuring a satisfactory level of quality, safety and effectiveness and, finally, improving the efficiency of drug distribution networks.

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The obstacles to local production and access to treatment in Africa

Philippe Abecassis, *Senior lecturer, Université Paris 13*
Nathalie Coutinet, *Senior lecturer, Université Paris 13*

Access to proper medicine is a major challenge for African countries. While the global market is mature and highly profitable, the African Continent has been left far behind despite enormous needs and huge growth potential. Securing proper patient access to drugs and improving Africa's integration into the global market for medicines means dealing with the challenges of product quality and availability as well as with financial accessibility.

Medicinal drug manufacturing is unequally distributed throughout the world. The African Continent only accounts for 3% of global output while 95% of the medicines consumed in Africa are imported. However, the situation differs widely from one country to another. South Africa and Morocco, the Continent's veritable "*pharmerging*" nations[1] manage to produce 70% to 80% of the drugs they need while certain central African countries need to import 99% of their medicinal requirements.

And yet with estimated annual growth of around 10% between 2010 and 2020 – the second-fastest growing market after the Asia-Pacific region – Africa represents a dynamic proposition. Although it only contributes a small proportion of global pharmaceutical sales, over the past few years its massive growth potential has led the *big pharma* (i.e., pharmaceutical multinationals) and Asian generic drug manufacturers **(see box opposite)** to start investing here[2] alongside local producers. However, all players have to deal with a fragmented market due to specific national historical features.

WEAKNESS OF AFRICAN OUTPUT

South Africa, the Continent's biggest producer, manufactures mainly for its own domestic market which is Africa's biggest and was worth USD 3.19 billion in sales in 2016[3]. The South-African Aspen Group, the fruit of a joint venture with GSK, is the Continent's biggest drug manufacturer. Although not as big, Moroccan-based Cooper Pharma, is still leader in its market and

1 ▸ Combination of "pharma" and "emerging".
2 ▸ From a growth perspective, South Africa, Nigeria, Ethiopia and Algeria are the most attractive markets.
3 ▸ The forecast rate of growth for 2016 and 2017 is 16.8%.

is busy setting up production facilities in Côte d'Ivoire and Rwanda in order to crack the West and East African markets (Logendra, Rosen and Rickwood, 2013). Morocco is the Continent's second-biggest producer with 40 production plants and 10% of output is exported.

Aside from South Africa and Morocco, production facilities are currently in the pipeline in Tanzania, Kenya, Uganda, Ethiopia, Ghana, Nigeria and Mozambique. More than 70% of Africa's production is met by the 10 countries[4] that also account for two-thirds of its GDP. Most producers are small local firms.

Local Northern and Southern African manufacturers produce both compounds under license and their own generic drugs, mainly for their domestic markets or those of adjacent countries, but they do not have the resources to invest in R&D in order to tackle neglected diseases or even to keep local markets fully supplied. They suffer from a lack of competitiveness: local circumstances are not always conducive to deploying the Good Manufacturing Practices (GMPs[5]) required to do business at international level and to guarantee sufficient quality and continuous production. Moreover, fragmented pharmaceutical markets, due to the complexity and chaos inherent in different legal frameworks, hamper the competitiveness of local African laboratories vis-à-vis Asian manufacturers of generic drugs. →

The major players in the pharmaceuticals sector

Global pharmaceutical production is dominated by the *big pharma*, the major – generally Western – multinationals (Pfizer, Novartis, etc.). They are present across the entire value chain (from R&D to product manufacturing) and hold the key patents for innovative compounds. These big firms are followed by medium-sized groups specialised in a specific product category or therapeutic domain such as Boiron Group (homoeopathy) and Amgen (biotechnology-based drugs). The advent of biotechnology in the 1990s gave rise to start-ups specialised in R&D and this enabled the *big pharma* to outsource the most complex and risky phases of R&D. Lastly, the growth in generic drugs in both Northern and Southern countries has witnessed the emergence of global generic drug manufacturers like India-based Cipla and Ranbaxy and the Israeli firm Teva. The growing tendency to outsource certain stages of the production process has also been conducive to the emergence of new sector players. Manufacturers of active ingredients, located mainly in China, produce the chemical substance that possesses a therapeutic effect. Outsourcers located in developing countries produce medicines for third parties while contract research organisations perform certain activities on behalf of pharmaceutical firms (clinical testing or preparing applications for marketing authorizations, etc.).

FOCUS

CENTRE D'ÉCONOMIE DE L'UNIVERSITÉ DE PARIS-NORD

Centre d'économie de l'université de Paris-Nord (CEPN) is a broad-ranging economics and management research unit attached to Université Paris 13. CEPN is structured around three key research themes: financial risks and regulation; political economy and applied macro-economics; and institutions, markets and intellectual property rights. The Centre's research tackles these three topics from a common structural analytical perspective of contemporary economies with a key emphasis on institutions and history.

4 ▸ Algeria, Egypt, Côte d'Ivoire, Kenya, Libya, Morocco, Nigeria, South Africa, Sudan and Tunisia.

5 ▸ As defined by the WHO, GMPs concern all aspects of manufacturing processes designed to "ensure that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification." GMPs must ensure proper traceability of all stages in the production process.

HEALTH SAFETY REQUIREMENTS AND INTELLECTUAL PROPERTY RIGHTS ARE HOLDING PRODUCTION BACK

Regulations concerning intellectual property rights **(IPR, see box below)** have really hit local producers in developing countries hard and basically prohibit them from legally producing copies of drugs that have been patented in Northern countries for their own markets.

Moreover – and this goes for all countries – new drug compounds require a marketing authorization that is only delivered following a series of very strict studies designed to test the drug's quality and safety. Drug manufacturers are subject to qualification procedures including compliance with GMPs. But few countries, particularly in Africa, have the reliable bodies that are needed to deliver such marketing authorizations and exercise any sort of effective control over the production of these products. This is why, in the specific case of priority diseases and at the request of certain procurement agencies, pre-qualification processes administered by the WHO have now been set up. However, because few African laboratories actually get this pre-qualification, international procurement agencies are turning to foreign competitors, especially those from India.

Consequently, international investment – notably from the World Bank which is unable to find sufficiently viable prospects – remains pitifully small. To help African countries deal with this handicap, *big pharma*, the WHO and NGOs such as UNITAID are offering to provide technical assistance to local producers to help them comply with GMPs and obtain pre-qualification from the WHO. At the end of the day, all of these regulations (i.e., concerning IPR and health safety) have a huge influence on the accessibility of medicines.

Intellectual property and medicines

Ever since the Agreement on Trade-Related aspects of Intellectual Property rights (TRIPS) signed at the WTO in 1994, medicinal drugs have been afforded global protection. These agreements fixed patent validity at 20 years (sometimes extended for another 5 years) and drew a distinction between patent-protected originator drugs, and unpatented generic drugs. However, under certain circumstances and subject to restrictive legal conditions, copies of patented drugs may be produced and distributed on a given local market under statutory or voluntary licensing arrangements. The declarations of Doha (2001) followed by Cancun (2003) provided for greater flexibility in this system. In particular, countries with statutory licenses were allowed to export part of their production to countries with insufficient or non-existent pharmaceutical production facilities. Despite this progress, certain African countries expressed reservations or requested clarifications. In January 2017, this process culminated in the adoption of a decisive amendment providing legal certainty that generic versions of patented drugs may be produced specifically for export under such arrangements (Abecassis and Coutinet, 2017).

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THE CHALLENGES OF ACCESSIBLE TREATMENT IN AFRICA

Although global production of medicine is massive and diversified, it is frequently geared to rich and profitable Western markets and ill-adapted to African realities. There is very little R&D investment in infectious diseases that are endemic to African countries. Consequently, the Continent suffers from major shortages in upstream availability of drugs. So for example, according to OXFAM France, between 1999 and 2004, only three new innovative compounds targeting diseases prevalent in tropical countries were launched on the market out of a total of 163 new drugs.

For all medicines, even those produced in accordance with international standards, problems with distribution can undermine supply at local level. The poor state of transport infrastructure, unreliable electricity supply and insufficient control can affect key components of the distribution process such as the cold chain, storage conditions and compliance with "sell-by dates". This is compounded by a highly fragmented distribution network: multiple distributors and wholesalers not only complicate distribution, they also push up prices (McCabe *et alii*, 2011). Such conditions are highly conducive to sub-standard and counterfeit medicines: in some African countries, counterfeit products represent half of all drugs on the market.

Obviously questions of financial accessibility or "affordability" are tied to the price but aside from the price fixed by the producer, governments can improve accessibility by picking up some or all of the costs of certain drugs. They can do this either by using subsidies or a system of social protection. Governments can also leverage customs duties, taxes, import duties and conditions for obtaining licenses.

However, such powers are frequently tempered by scarce resources and in some African countries, expenditure on medical drugs eats up as much as 30% of the health budget. Despite the major changes of the past few years, few countries have been able to set up a proper health and welfare system. Exceptional rates of public health insurance in Rwanda (91%) or Morocco (62%) mask the bigger picture: coverage is only 13.3% in Mauritania or a mere 3% in Burkina Faso (Del Hierro and Lambert, 2016). Consequently, in a lot of African countries, NGOs and bilateral aid play a big part in access to medicines.

"Although global production of medicine is massive and diversified, it is frequently geared to rich and profitable Western markets and ill-adapted to African realities."

By analysing three criteria that influence the accessibility of medicines (availability, quality and affordability), we note that accessibility is a function of the combined actions of several types of actors: various ministries (Health, Trade, Finance, etc.), different structures in the medical drug supply chain (medical drug agencies, central procurement and distribution organisations, quality control agencies, certification bodies), different national and international financial backers, health centres (clinics and treatment centres, hospitals and biological laboratories), healthcare workers, patients' associations and civil society organisations. ■

The essential transformation of supply chains in the sub-Saharan pharmaceutical sector

Natasha Sunderji, *Global Health Lead, Accenture Development Partnerships*

In Sub-Saharan Africa, integrated technology-enabled distribution networks can increase access, enhance quality and lower the prices of medicines.

FOCUS
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Accenture Development Partnerships works with leading international development organizations to address the world's social, economic and environmental issues. By delivering the power of Accenture's global capabilities and experience, we help our clients develop sustainable, innovative and market-based solutions to maximize value while driving measurable impact.

Sub-Saharan Africa's pharmaceutical market represents a huge opportunity for private sector investors and those looking to expand global health impact. Pharmaceutical sales are projected to grow from $4bn in 2003 to $50bn in 2020[1]. In half of all countries in Sub-Saharan Africa, only 10% of the growing population is served by social health protection. Private sector investment and innovation will be essential to meeting the demands of a population that is growing extremely rapidly and whose pharmaceutical usage is increasing steadily.

A FRAGMENTED SUPPLY CHAIN

However, private sector pharmaceutical supply chains and retailing in Sub-Saharan Africa are highly fragmented. This fragmentation is the key factor behind patient challenges around drug pricing, quality, availability, and counterfeiting, and is largely driven by infrastructural gaps. There are numerous "middle men" in the supply chain, meaning there can be hundreds of different businesses in pharmaceutical distribution and retailing in a country. Ghana has over 500 businesses involved in pharmaceutical wholesale to distribute medicines, which are sold through over 700 official retailers, with an even larger informal market. Middle men in the supply chain, or sub-distributors, each add their own mark-up of around 25% to the final price of medicines.

> "Private sector pharmaceutical supply chains and retailing in Sub-Saharan Africa are highly fragmented."

1 ▸ Sources: 'Africa's Life Expectancy Jumps Dramatically', Financial Times, 2016 - https://next.ft.com/content/38c2ad3e-0874-11e6-b6d3-746f8e9cdd33 Population Reference Bureau, http://www.prb.org/pdf13/2013-population-data-sheet_eng.pdf, Health expenditure, total (% of GDP), World Bank - http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS/countries/1W?display=graph, FiercePharma, Quartz, McKinsey

This means that despite a potentially low ex-manufacturer price, medicines in Sub-Saharan Africa are often the most expensive in the world. In Kenya, only 48% of the final private sector drug price to a patient is the manufacturer's price, while 22% is the wholesaler margin, 21% is the retail margin, and 9% is the price of local repackaging. By contrast, wholesaler margin in the USA, an extremely consolidated market, is approximately 4% of the final patient price.

Even if patients can afford extremely high medicine prices, finding it when needed remains yet another challenge. Medicines are inevitably delayed in their journey through multiple supply chain actors towards the final patient. This problem is particularly acute in places like Mozambique, which has a large landmass and many actors working to move medicines around the country. Stocks can be delayed at storage facilities for up to 5 months, which means retailers struggle to maintain adequate stock levels.

"Even if patients can afford extremely high medicine prices, finding it when needed remains yet another challenge."

POOR QUALITY AND COUNTERFEIT MEDICINE

Obtaining medicine of high quality also becomes more difficult when supply chains are so fragmented. When stocks are delayed, the risk of medicines with a short shelf life being wasted or becoming ineffective increases dramatically. Retailers who need stock are less likely to insist on working with distributors who only provide drugs produced by pre-qualified manufacturers. Further, patients who cannot find the medicine they need through the formal market are more likely to be driven to the informal market, or be forced to use medicine of poor quality. An even more serious problem than poor quality medicine is counterfeit medicine. While there are numerous complex factors that contribute to the global counterfeiting problem, a highly fragmented supply chain with multiple layers is an exacerbating factor. Counterfeit medicines are more likely to be sold through unlicensed outlets (51%) vs. licensed outlets (24%)[2]. With fake malaria and tuberculosis drugs contributing to approximately 700,000 deaths globally each year[3], it's clear that high levels of supply chain complexity are unsustainable if we truly seek to improve the lives of those living in sub-Saharan Africa. →

"High levels of supply chain complexity are unsustainable if we truly seek to improve the lives of those living in sub-Saharan Africa."

2 ▸ Substandard and counterfeit medicines: a systematic review of the literature. 2013. http://bmjopen.bmj.com/content/3/8/e002923
3 ▸ UN, http://www.un.org/africarenewal/magazine/may-2013/counterfeit-drugs-raise-africa%E2%80%99s-temperature

A CONSOLIDATED AND MORE EFFICIENT MARKET

Consolidating the pharmaceutical supply chain can have a transformative impact and result in lower prices and more abundant, high quality medicine. The transformation of the Mexican pharmaceutical supply chain provides clear evidence that consolidation can be a key part of the solution. Mexico is now the twelfth largest pharmaceutical market in the world, worth $13bn, and has had great success in improving the availability of quality medicines for patients.

> "Regulators have a supporting role to play in driving down the prices of medicine and driving up their quality."

The formerly fragmented retail landscape is now dominated by several major retail pharmacy chains, including Farmacias YZA with over 550 stores and Farmacias Guadalajara with over 1,550 stores. Large retail pharmacy chains are able to better control their stock levels and implement supply chain traceability systems that help ensure that high quality medicines are sold to patients. These pharmacy chains also use their scale to provide exceptional services to patients such as online purchasing and 24-hour emergency outlets. The distribution market in Mexico is similarly consolidated. The four major distributors (Nadro, Casa Marzam, Farmacos Nacionales and Almacén de Drogas) hold a total market share of 58%, and are able to transport medicines rapidly and respond to fluctuating demand.

While regulators have a supporting role to play in driving down the prices of medicine and driving up their quality, they also have the power to encourage consolidation of the market. Private equity investment has already begun to lead the charge in consolidating the pharmaceutical supply chain. Leapfrog Investments is one key player active in this space. LeapFrog has invested in Goodlife Pharmacy. Goodlife's business model, incorporating telemedicine services and a sophisticated payments platform alongside their core pharmacy offering has been a standout success story in the region. Today the retail pharmacy chain reaches over 600,000 customers across more than 20 locations in East Africa. The capital injection that Goodlife has received from LeapFrog will facilitate an aggressive expansion strategy across the region in the coming years helping to create an innovative player of real scale in Kenya and beyond. The business is transforming the way patients in East Africa find and buy medicine. A highly fragmented web of hundreds of small retailers could never replicate the impact that chains like Goodlife are having on patients.

International corporates can also play a major role in driving consolidation. This is particularly evident again in the transformation of the Latin American market. Mexican beverage and retailing conglomerate FEMSA acquired market leading regional pharmacies such as Farmacias YZA in Mexico and Cruz Verde in Chile. FEMSA has ambitious plans to grow both brands, which could expand their ability to reach vast numbers of patients with affordable, high quality medicine.

> "The formerly fragmented retail landscape is now dominated by several major retail pharmacy chains [(...)that] are able to better control their stock levels and implement supply chain traceability systems."

Consolidation through private equity investment and corporate M&A has proven to be a successful strategy in transforming pharmaceutical supply chains. However, there is an opportunity to take this even further. Emerging technologies that require limited capital investment can help drive transformation, making supply chains more efficient without exorbitant cost and time commitment. Sub-Saharan Africa is one of the most exciting test cases for this in the world. Gaps in pharmaceutical regulation and long-standing infrastructural challenges do not need to inhibit the development of innovative solutions that help patients find affordable medicine. Silicon Valley startup Zipline, for example, is developing technology with the potential to be a game-changer for pharmaceutical distribution. Backed by venture capitalists including Sequoia Capital and Andreessen Horowitz, they have developed unmanned aerial vehicles (UAVs) with built-in GPS systems to deliver parachute-equipped boxes weighing up to 1.5kg. This solution is currently being used to supply blood and vaccines to rural regions in Rwanda and as a consequence patients in such underserved areas now have a much higher chance of receiving timely, quality medicine. Similarly, the Government of Malawi and UNICEF are partnering with US company, Matternet, to test the use of UAVs to reduce the waiting time for HIV testing of infants. Also backed by Andreessen Horowitz, Matternet is working with a number of international partners, including the WHO and MSF, to apply cutting-edge technology to solve supply chain challenges. As the cost of such technologies decreases over time, drones and other innovations could significantly streamline pharmaceutical supply chains and replace middle men, resulting in affordable, traceable, quality medicines for all.

> “The current complexity of pharmaceutical supply chains drives so many of the problems that patients face in accessing timely, affordable, high-quality medicines.”

The public sector will not be able to meet the rapidly increasing demands of sub-Saharan Africa alone. The current complexity of pharmaceutical supply chains drives so many of the problems that patients face in accessing timely, affordable, high-quality medicines. The private sector has a vital role to play in driving greater efficiency and transparency. Consolidation is the first obvious option and is yielding great results. Transforming business models by leveraging technology-enabled solutions is the next step and can differentiate market leaders. Those who recognize the market potential in sub-Saharan Africa and act early will not only reap financial rewards, they will also contribute to saving millions of lives. ■

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From warehouse to patient: mPharma's approach to increasing the accessibility of medicine in Africa

Gregory Rockson, *CEO of mPharma*

Since 2013, the start-up mPharma has been trying to build an infrastructure and a drug monitoring system to connect patients, hospitals and pharmacies. The objective is to enable doctors to know the exact location and availability of medicines in real time, and to provide patients with better access to medicines.

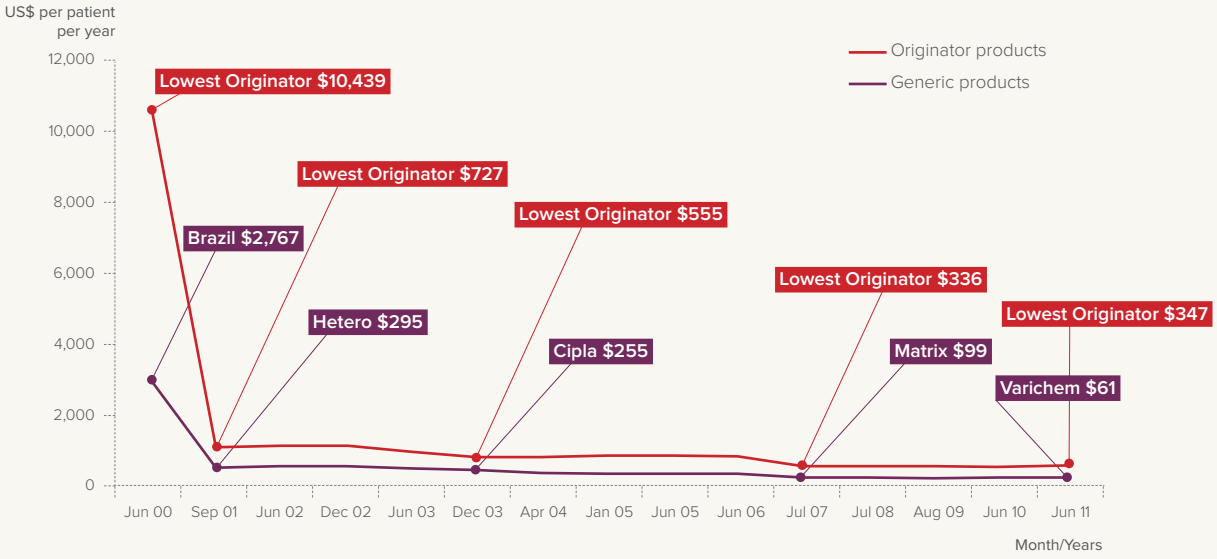
One of the greatest modern day success stories in global health has been the reduction in the yearly price of branded HIV/AIDS drug prices from a high of $10,439 in 2000 to $347 by 2011. During the same period, the introduction of generic drug treatments dropped a year's worth of treatment to about $61, as shown in the graph from Doctors Without Borders **(see diagram ⊕ opposite)**. With financial support from organizations like the Global Fund, PEPFAR and the Clinton Foundation, more than 5 million patients in Sub-Saharan were on treatment by 2011[1].

While a lot more work needs to be done to ensure that 100% of HIV/AIDS patients in Africa get on treatment, the achievement thus far has been nothing short of spectacular and highly commendable. It shows that when different stakeholders in the healthcare ecosystem come together with a singular vision, miracles can be created. mPharma has learned from this achievement to re-imagine how pharmaceuticals are procured, prescribed and dispensed in Africa.

> "When different stakeholders in the healthcare ecosystem come together with a singular vision, miracles can be created."

1 ▸ UNAIDS, *2012 UNAIDS Report on the Global AIDS Epidemic*, 2012.

HIV combo drug prices, from 2000 to 2011



Source: Doctors Without Borders (MSF), *Untangling the web of antiretroviral price reductions*, 2011 (p.7). Available at: https://d2pd3b5abq75bb.cloudfront.net/2012/07/16/14/42/23/52/UTW_14_ENG_July2011.pdf

WHAT IS MPHARMA?

mPharma is a prescription drug manager for providers and payers in Africa. mPharma manages the drug inventory for providers and designs drug benefits plan for payers. mPharma currently operates in 3 African countries (Nigeria, Ghana and Zambia), serving close to 20,000 patients each month across a network of over 70 hospitals and clinics in Lagos, Warri, Port Harcourt, Benin, Aba, Accra, Kumasi, Cape Coast, Lusaka and Ndola. mPharma aims to build the data intelligence and retail layer to support the future of African healthcare.

If CVS Health, QuintilesIMS and McKesson[2] had a baby, it would be called mPharma. mPharma is building a more scalable version of CVS Health in Africa using the Airbnb model. This model enables mPharma to create a tightly coupled pharmacy monolith (on a continent that has a highly fragmented pharmacy retail market) with leverage over pricing, distribution and reimbursements.

mPharma has developed supply chain software that enables us to implement vendor managed inventory for independent healthcare providers in Africa. mPharma takes over inventory procurement of retail and hospital pharmacies while remotely running pharmacy operations using proprietary technology infrastructure. This entails using data we generate through our software to forecast demand, and commanding lower pricing from suppliers (distributors and manufacturers) due to aggregated and predicted volumes across hospitals and retail pharmacies in our network. →

FOCUS
MPHARMA

mPharma is a venture-backed startup whose mission is to make prescription drugs in emerging markets easily accessible, and easily affordable. mPharma has partnered with major pharmaceutical manufacturers, insurance companies, financial institutions and governments to deliver medicines directly to consumers in underserved markets.

2 ▸ CVS Health is the largest pharmacy chain in the US. QuintilesIMS is the leading provider of insights and analytics for companies in the healthcare industry. Mckesson is the biggest pharmaceutical distributor in the US.

mPharma supplies drugs to all pharmacies on consignment. Thus, revenues are based on actual drug sales to patients, and not what mPharma supplies to hospitals on a timed basis. This creates a disruptive business model for hospitals and pharmacies because it is different from the traditional "pay for supplies" model that distributors offer. This model improves working capital and cash flow for hospitals and pharmacies.

A BETTER SUPPLY CHAIN MODEL FOR IMPROVING AVAILABILITY AND ACCESSIBILITY

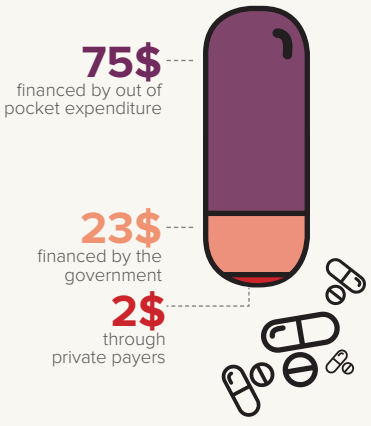
> "We need to rethink how patients pay for healthcare whether through government backed insurance programs or innovative payment models for out-of-pocket expenditures."

The drug supply chain in Africa is built on a "Push" data model. This means, distributors have to wait to receive a purchase order from providers before supplying drugs to them. The Push model is built on siloed data systems between distributors and providers. As a result, both parties are unable to forecast demand which leads to frequent stockouts.

A "Pull" model is based on an integrated data system that gives distributors real time access to anonymized patient level dispensation data from providers. Instead of waiting for a provider to send a purchase order before supplying drugs, a distributor can use the dispensation data they receive to set appropriate re-order levels. A new purchase order is automatically triggered when the stock reaches the reorder level and prompts the distributor to supply drugs without needing the input of the provider. The financial interests of the provider are aligned with those of the distributor if the stock is provided on a consignment basis. This enables the distributor and provider to create a tightly coupled monolith that can aggressively negotiate prices with pharmaceutical manufacturers.

BETTER PAYMENT MODELS FOR IMPROVED PATIENT ACCESS

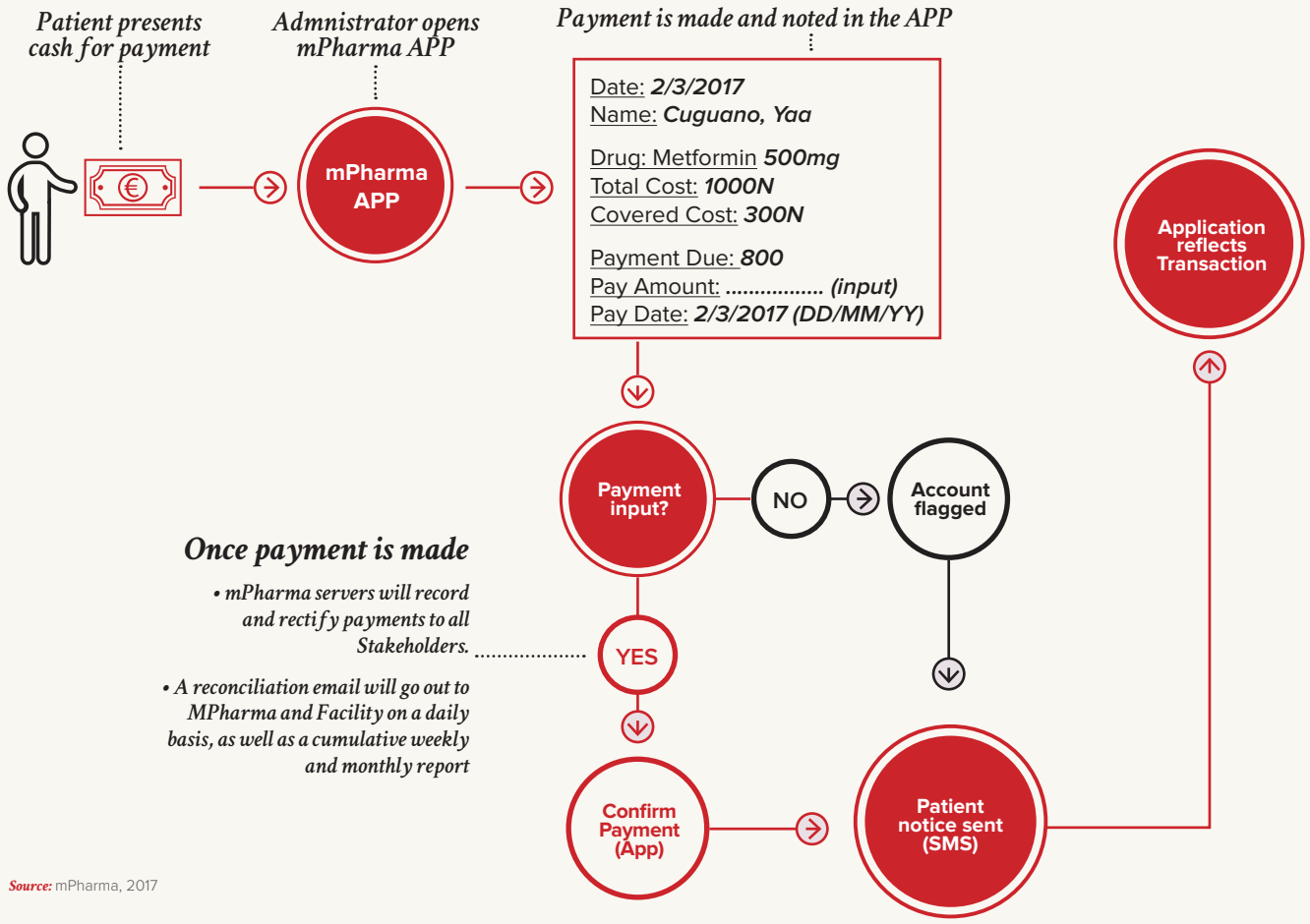
Out of 100 dollars of health spending in Nigeria



According to the WHO, for every $100 spent on healthcare in Nigeria, $23 is financed by the government, $2 through private payers and an overwhelming $75 through out of pocket expenditure. Approximately 90% of the African patient population is paying out-of-pocket for services. The affordability of medication for out-of-pocket patients has been linked to behaviours that have further exacerbated chronic conditions. Research shows that adherence to treatment can be influenced by inability to finance the treatment specifically targeting drugs for non-communicable and chronic diseases (e.g. oncology, cardiovascular treatments).[3] mPharma aims to create a program that bridges the gap between financial constraints and non-adherence, ultimately increasing both patient adherence and patient wellbeing. By spreading the cost of a drug over a long period of time for patients that are creditworthy, mPharma aims to minimize the influence of cost on medicine use **(see diagram p.17)**.

3 ▸ https://cvshealth.com/thought-leadership/cvs-health-research-institute/cost-biggest-barrier-medication-adherence

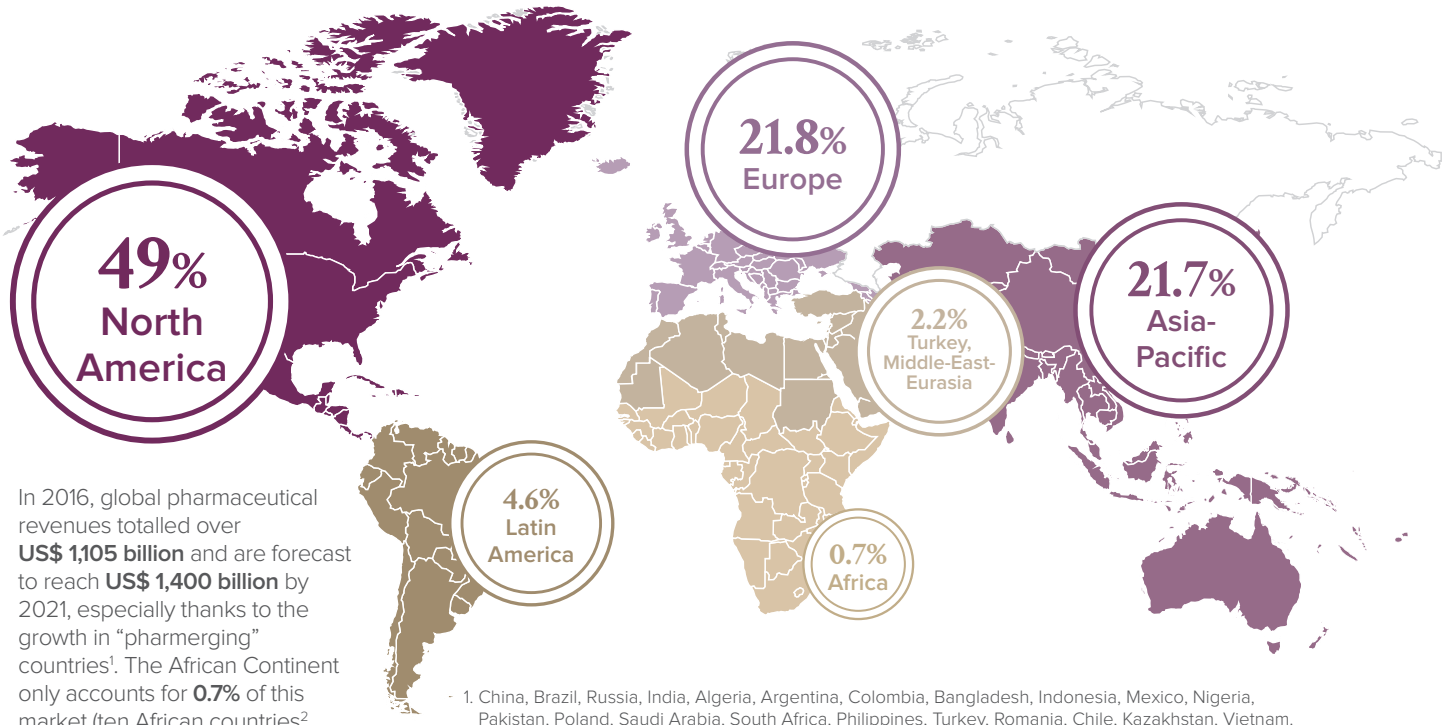
How mPharma works



Source: mPharma, 2017

We need to rethink how patients pay for healthcare whether through government backed insurance programs or innovative payment models for out-of-pocket expenditures. We cannot improve and guarantee access to innovative treatments if we don't fix the cost structure for delivering healthcare. According to the Aon 2018 Global Medical Trend rates survey, the Middle East and Africa saw the 2nd highest net growth rates in medical costs at 7.6% compared to the global average of 5.4%. This growth is due to a rise in the incidence rates for non-communicable diseases. This trend will only get worse if we don't take a more proactive approach to reducing the cost of drug treatments. mPharma wants to play a small role in ensuring each patient gets the drug they need irrespective of their socio-economic status. Especially with Mutti, offering available high-quality medication (e.g. oncology, cardiovascular treatments... usually high-cost drugs) at affordable prices to the patients.

Africa within the global pharmaceutical market

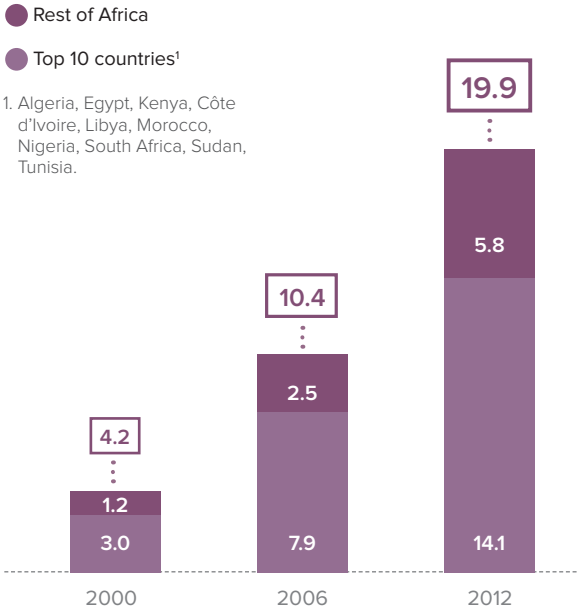


In 2016, global pharmaceutical revenues totalled over **US$ 1,105 billion** and are forecast to reach **US$ 1,400 billion** by 2021, especially thanks to the growth in "pharmerging" countries[1]. The African Continent only accounts for **0.7%** of this market (ten African countries[2] represent 70% of the Continent's revenues on their own).

1. China, Brazil, Russia, India, Algeria, Argentina, Colombia, Bangladesh, Indonesia, Mexico, Nigeria, Pakistan, Poland, Saudi Arabia, South Africa, Philippines, Turkey, Romania, Chile, Kazakhstan, Vietnam.
2. Algeria, Egypt, Kenya, Côte d'Ivoire, Libya, Morocco, Nigeria, South Africa, Sudan, Tunisia.

Source: IQVIA Institute; World Health Organisation (WHO)

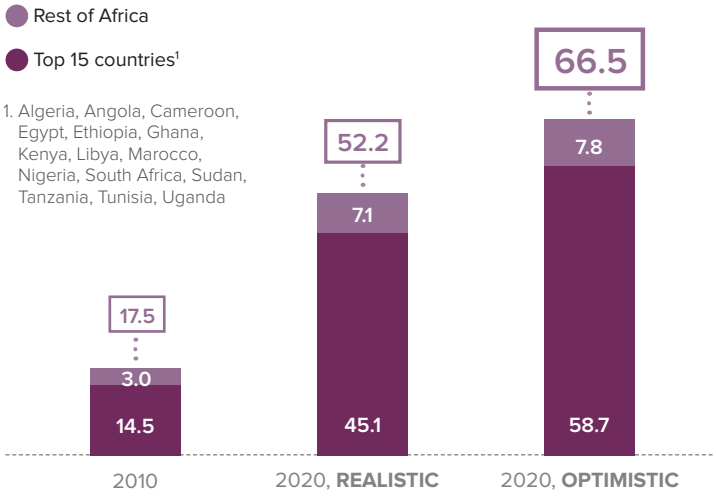
Market size, US$ billions



Source: McKinsey, *Africa: A Continent of Opportunity for Pharma and Patients,* April 2015

The African pharmaceutical market is booming

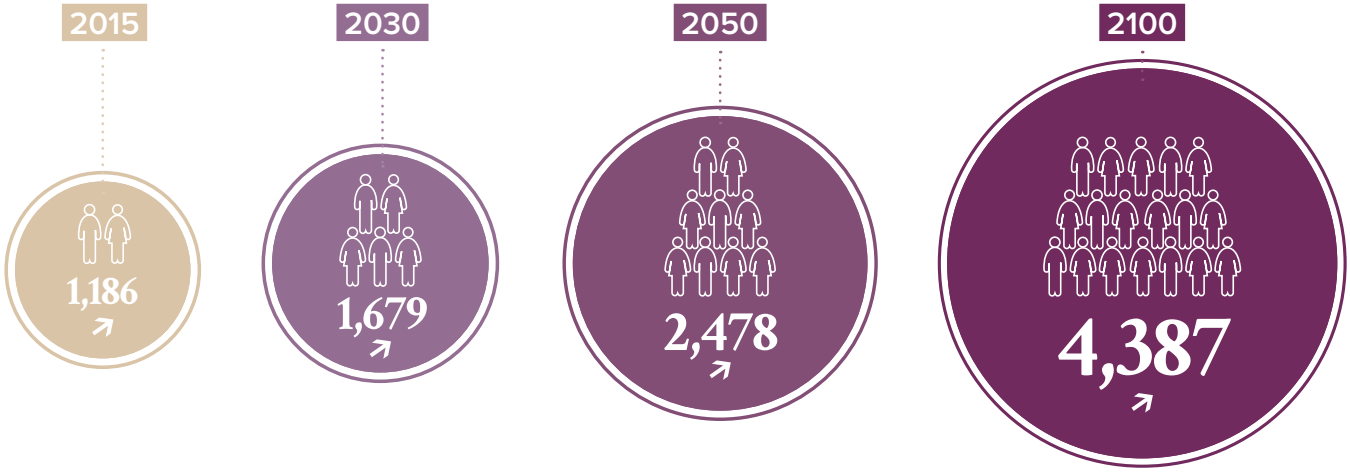
The African pharmaceutical market was worth **US$ 19.9 billion in 2012** and is forecast to grow to **US$ 50 billion by 2020,** driven by the Continent's demographic boom *inter alia.*



Source: McKinsey, *Africa: A Continent of Opportunity for Pharma and Patients,* April 2015

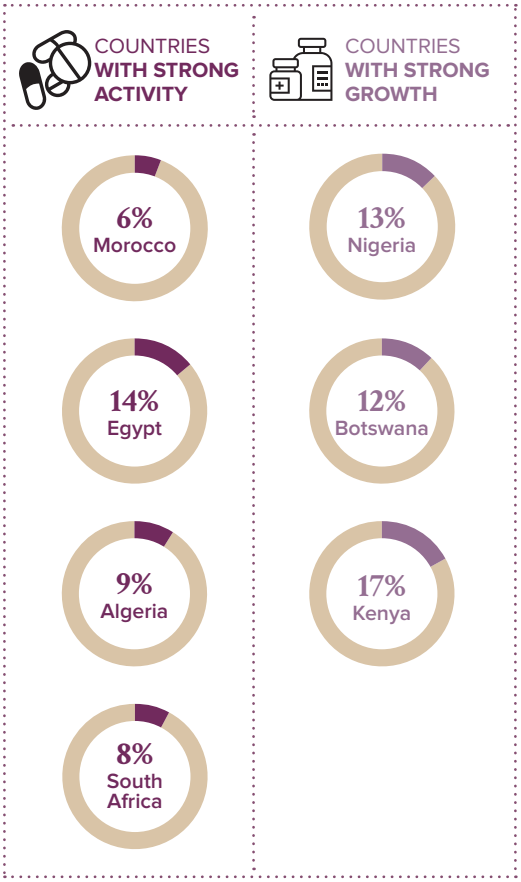
A population forecast to boom

Population of Africa (millions)



Source : United Nations World Population Prospects: *The 2015 Revision,* 2015, IQVIA Institute

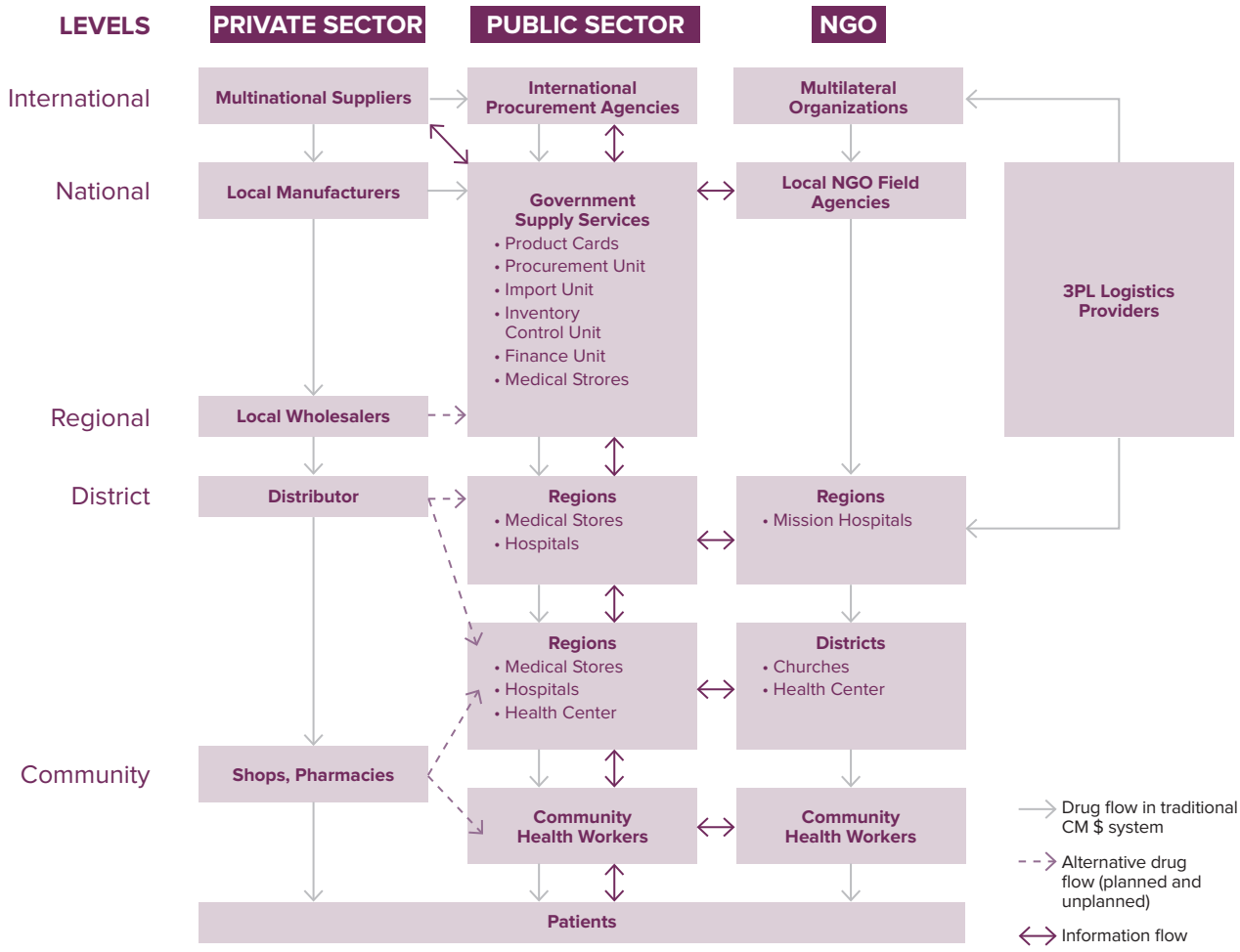
Average annual growth in pharmaceutical sales (2011 – 2016)



Source : IQVIA Institute

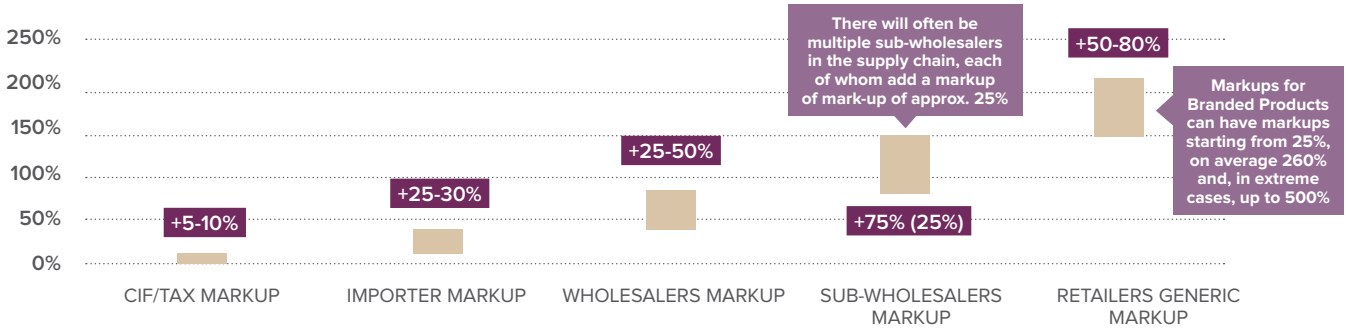
Pharmaceutical industry and emerging markets

Pharmaceutical supply chains in emerging markets



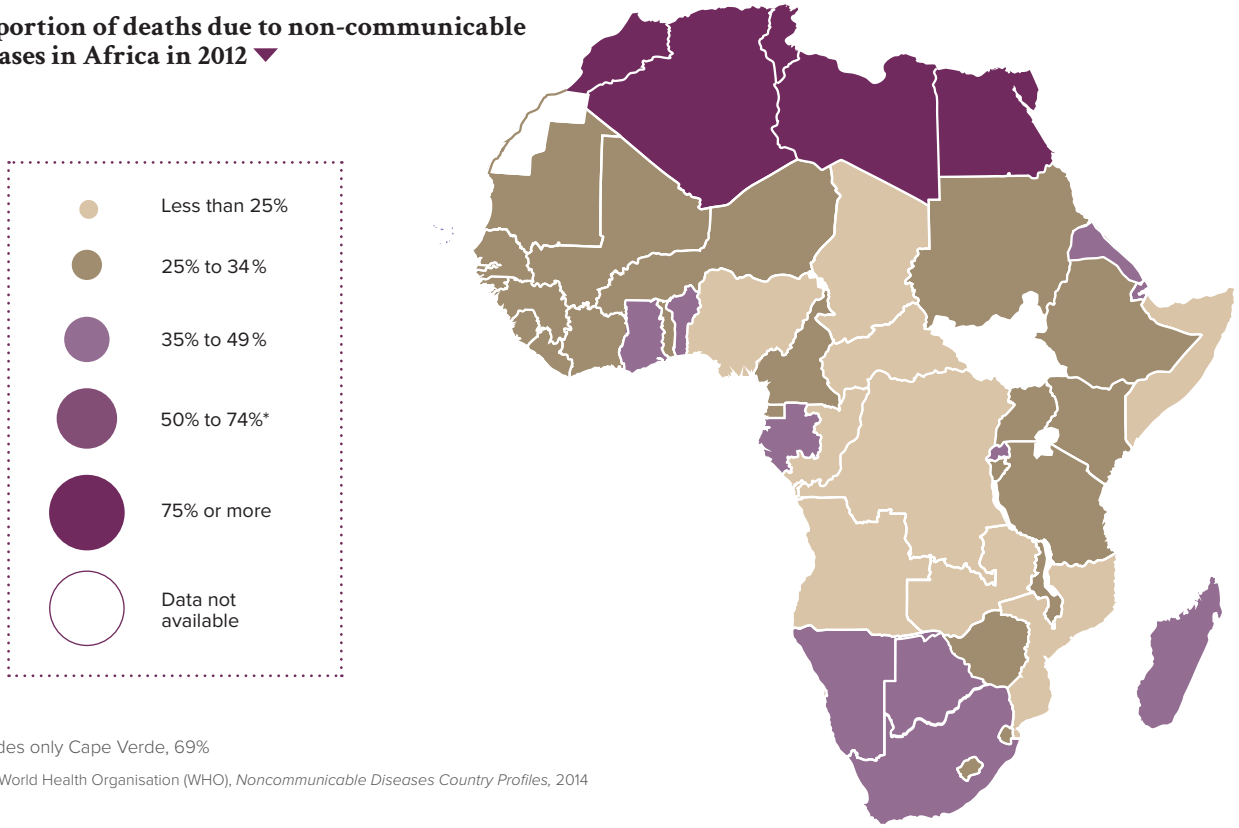
Source: International Finance Corporation (IFC), *Private Sector Pharmaceutical Distribution and Retailing in Emerging Markets*, 2017

Average mark-ups on medicines in emerging markets



Source: International Finance Corporation (IFC), *Private Sector Pharmaceutical Distribution and Retailing in Emerging Markets*, 2017

Proportion of deaths due to non-communicable diseases in Africa in 2012



*Includes only Cape Verde, 69%

Source: World Health Organisation (WHO), *Noncommunicable Diseases Country Profiles*, 2014

Consolidation of pharmaceutical distributors and retail chains

CATEGORY	RESTRICTED BY LAW OR REGULATION	MOSTLY FRAGMENTED	INITIAL CONSOLIDATION	MODERATE CONSOLIDATION	CONSOLIDATED
DESCRIPTION	Retail pharmacy or wholesaler/distributor consolidation is restricted by national law or regulation	Thousands of wholesalers/distributors with no clear set of market leaders	Initial stage of market consolidation with more than one retail pharmacy chain growing beyond 5 stores	National or city-level retail pharmacy chains exist	50%+ of the retail pharmacy market is consolidated into an oligopoly
EXAMPLE COUNTRIES	▸ Cambodia ▸ Cameroon ▸ Côte d'Ivoire ▸ Uganda ▸ Egypt ▸ Morocco ▸ Turkey ▸ Vietnam	▸ Malawi ▸ Mozambique ▸ Nigeria ▸ Sudan ▸ Guatemala ▸ Kazakhstan	▸ Ghana ▸ Algeria ▸ India	▸ South Africa ▸ Latin America, Brazil, Peru, Mexico, Chile ▸ China	▸ Mali ▸ US ▸ UK ▸ Philippines

Source: International Finance Corporation (IFC), *Private Sector Pharmaceutical Distribution and Retailing in Emerging Markets*, 2017

Patent pooling mechanism: promoting innovation and improving access to medicines in Africa

Esteban Burrone, *Head of Policy, Medicines Patent Pool*
Erika Dueñas, *Policy and Advocacy Manager, Medicines Patent Pool*

"Public health" oriented licenses and patent pooling in Africa promotes research and production of affordable, high quality generic treatments for AIDS, hepatitis C and tuberculosis.

FOCUS
MEDICINES PATENT POOL

Founded in 2010 by Unitaid, the Medicines Patent Pool (MPP) is a public health organisation working to improve access to affordable and appropriate HIV, hepatitis C and tuberculosis medicines in low- and middle-income countries. The MPP works with a range of partners – industry, civil society, international organisations, patient groups and governments – to prioritise and license new and existing medicines.

The United Nations Sustainable Development Goals highlight the need to increase access to essential, high-quality, safe, effective and affordable medicines for all, a major public health challenge for African countries. Three specific diseases have a major impact on the economic and social development of Africa: namely HIV, hepatitis C and tuberculosis. These three diseases represent a significant public health burden in low-and middle-income countries generally and in Africa in particular. 26.6 million people are estimated to be living with HIV in Africa, many of whom contract tuberculosis, which remains the leading cause of mortality among people living with HIV. It is estimated that there are 2,720,000 new cases of tuberculosis every year in the African continent. With respect to hepatitis C, despite the new direct acting antivirals with cure rates exceeding 90%, only about 6% of people with hepatitis C in Africa have been tested for HCV and only 2% of those diagnosed with HCV have started treatment.

> "Three specific diseases have a major impact on the economic and social development of Africa: namely HIV, hepatitis C and tuberculosis."

To address many of the innovation and access challenges relating to diseases that disproportionally affect developing countries, the World Health Assembly approved the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA) in 2008. In the strategy, Member States agreed to promote new thinking in innovation and access to medicines, which would encourage needs-driven research to target such diseases. This is the case, for example, with patent pooling and voluntary licensing, tools on which Medicines Patent Pool has based its approach.

PATENT POOLING AND THE ESTABLISHMENT OF THE MPP

The Medicines Patent Pool (MPP) was established in 2010 with the financial support of UNITAID, the innovative financing mechanism hosted by the WHO, to promote access to new patented HIV medicines in low and middle-income countries through voluntary[1] licensing and patent pooling[2]. The MPP negotiates licence agreements on HIV, hepatitis C, and tuberculosis medicines with patent holders. These licences allow generic pharmaceutical companies to manufacture and distribute patented medicines in developing countries.

> "The commitment from pharmaceutical companies to work with the MPP has been key to improving access to new HCV and HIV drugs."

Competition between low-cost manufacturers brings prices down. The licences also provide the freedom to develop new treatments such as fixed-dose combinations and formulations adapted for children.

HOW THE MPP WORKS

The MPP model **(see diagram ⊕ p.25)** works for all stakeholders. Patent holders have an effective way to share patents on their products in resource-poor settings and may be compensated by royalties. Generic manufacturers are able to produce affordable new medicines more easily and rapidly. Donors and developing country governments are stretching their budgets further to treat more people. And people living with HIV, tuberculosis and hepatitis have more rapid access to the medicines they need at affordable prices.

The public health-oriented terms and conditions in MPP licence agreements seek to improve treatment options for the broadest number of people living in low and middle-income countries. The provisions include wide geographical scope; non-exclusive licences to encourage generic competition; compatibility with the use of TRIPS flexibilities related to public health; waivers for data exclusivity protection; disclosure of company patent information; and unprecedented transparency. The full text of all licences is published on the MPP website.

The commitment from pharmaceutical companies (originators and generic) to work with the MPP has been key to improving access to new HCV and HIV drugs. To date, the MPP has signed agreements with nine patent holders for twelve HIV antiretrovirals, two hepatitis C direct-acting antivirals, and one tuberculosis treatment. Its generic partners have distributed 12.9 million patient-years of WHO-recommended HIV, hepatitis C and tuberculosis medicines to 131 countries.

The MPP has signed licensing agreements with AbbVie, Bristol-Myers Squibb, Gilead Sciences, Johns Hopkins University, MSD (Merck & Co in the USA and Canada), Pharco Pharmaceuticals, Roche, ViiV Healthcare, the University of Liverpool and the US National Institutes of Health.

The MPP has also sublicensed to 20 generic manufacturers and product developers who are currently developing, producing, registering and supplying medicines at a lower cost. →

1 ▸ Patent holders may, at their discretion, grant other stakeholders exclusive or non-exclusive licences to manufacture, import and/or distribute a pharmaceutical product.
2 ▸ The idea is to pool patents, often held by different owners, so that their exploitation rights can be offered simultaneously in a single licence.

ENSURING ACCESS TO QUALITY MEDICINES IN AFRICA

The MPP's licences allow generic manufacture of patented antiretrovirals (ARVs) recommended by the WHO for first- and second-line treatments[3] for adults and children of different age groups. All countries in Sub-Saharan Africa are included in MPP's licences. Licences also include new promising ARVs that likely will be central to treatment in the future. For example, the MPP is also working with its manufacturing partners to ensure the most recent HIV medicines, such as dolutegravir (DTG) and tenofovir alafenamide (TAF) become available rapidly in developing countries from multiple manufacturers. DTG is considered a major advance in HIV treatment and is already a part of 1st line treatment recommendations of the WHO.

> "Licences from multiple pharmaceutical companies via the MPP have enabled the development of the new first line HIV fixed dose combination."

MPP licences enable the manufacturing of generic ARVs and their sale in countries where between 87% and 91% of people with HIV in the developing world live. This includes all low-income countries and 50-80% of World Bank classified middle-income economies.

The inclusion of public health oriented terms and conditions is a key distinctive feature of MPP licences. The Access to Medicine Index (ATM Index) that analyses 20 of the world's largest research-based pharmaceutical companies on their commitment to making medicines, vaccines and diagnostics more accessible, has recognised the terms and conditions of the MPP licences as being pro-access, flexible and broad in geographical scope.

The MPP is currently managing more than 100 pharmaceutical development projects with manufacturers to help speed up the availability of quality-assured generic versions of new treatments, including new fixed-dose combinations. Sublicences with generic manufacturers and product developers are already enabling the development, manufacturing and sale of HIV and hepatitis C medicines in a large number of developing countries.

THE EXPERIENCE OF MPP ON FACILITATING INNOVATION

The MPP licences provide the freedom to develop new treatments such as fixed-dose combinations – single pills composed of several medicines – and special formulations for children.

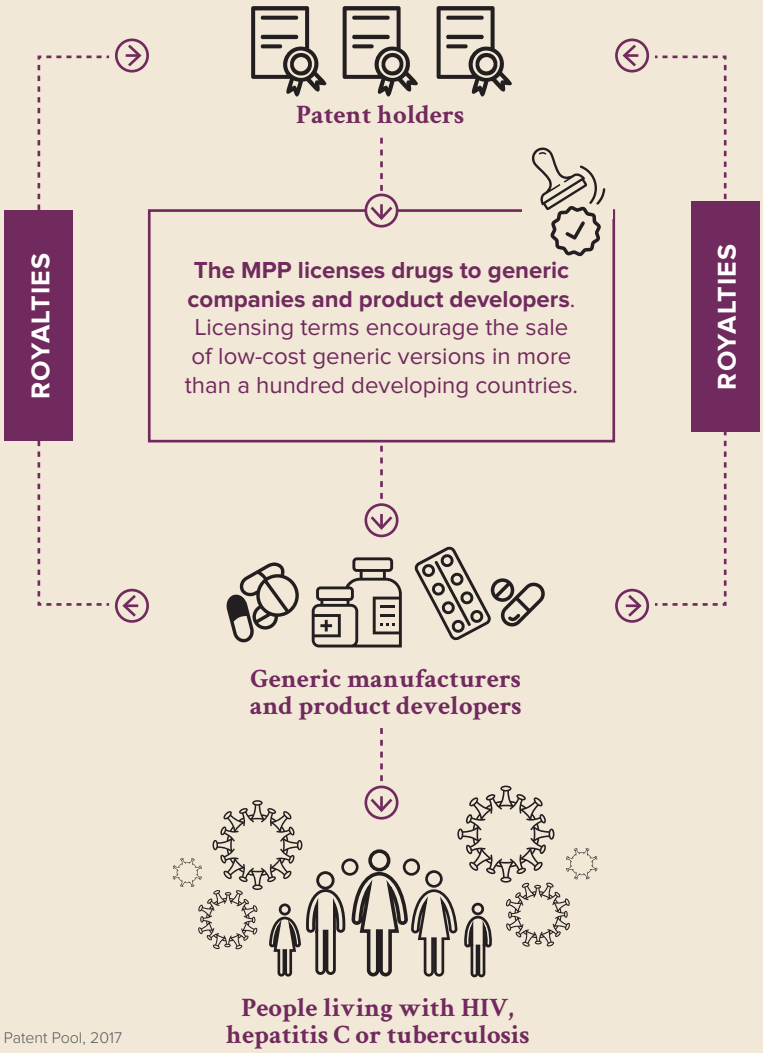
Licences from multiple pharmaceutical companies via the MPP have enabled the development of the new first-line HIV fixed dose combination, namely the combination of tenofovir disoproxil fumarate/lamivudine/dolutegravir, which was approved by the US FDA in August 2017. This is a new combination that will likely revolutionize HIV treatment in countries most affected by the epidemic, such as those in sub-Saharan Africa. In view of the multiple manufacturers working on its development, it is expected that the new formulation will not only offer a more effective and better tolerated treatment, but will also be available at more affordable cost than the currently used first-line treatment, enabling HIV treatment budgets to go further and treat more people.

The Medicines Patent Pool also engages partnerships with key stakeholders for innovation in other areas, such as the development of new paediatric HIV formulations and the development of new regimens for the treatment of multi-drug resistant tuberculosis.

Recently, the WHO and the Lancet Commission on Essential Medicines Policies recommended that consideration be given to the expansion of the MPP's patent pooling model to all patented essential medicines. Currently the MPP is exploring the feasibility, desirability and potential public health impact of expanding the patent pooling model to all patented essential medicines.

3 ▸ In resource-limited countries, treatment regimens are simplified, standardized and grouped under two effective options to be used one after the other (first and second line or first and second intention).

How the patent pooling mechanism works



Source: Medicines Patent Pool, 2017

Public health oriented licensing and patent pooling can play a key role in promoting innovation and access to meet the needs of African countries that are mostly affected by the HIV, TB and HCV epidemics. The MPP model is working in HIV, TB and HCV and has the potential of meeting access challenges in other disease areas. The MPP is unique in its approach to partnering with a range of public health actors, including the pharmaceutical industry and other stakeholders in the field of HIV, hepatitis C and tuberculosis, to support better access to essential drugs in Africa and in other developing countries. It also offers a mechanism to facilitate further innovation to address specific formulation needs in developing countries. The Medicines Patent Pool's work depends on collaboration and its partnerships with patent holding companies as well as with the generic manufacturers are critical to its success. ■

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Quality medicines in Africa: the importance of good knowledge of the supply chain and synergy between regulators and industry

Benedetta Schiavetti, *pharmacist and researcher, Quamed*

Pharmaceutical production has grown globally over the last decades: active ingredients and finished products are manufactured across different regions, and circulate through multiple distribution channels. Sadly, globalisation of production has not been accompanied by a strengthening of the regulatory systems worldwide: many national medicine regulatory authorities (NMRAs), especially in sub-Saharan Africa, are under-resourced and struggle to control their markets.

CONTEXTE

This article is co-authored by Raffaella Ravinetto and Daniel Vandenbergh. It is largely based on a paper previously published in the Journal of Pharmaceutical Policy practice: Ravinetto R, Vandenbergh D, Macé C et al. Fighting poor-quality medicines in low- and middle-income countries: the importance of advocacy and pedagogy. *J Pharm Policy Pract* 2016; 9:36. Available from: https://joppp.biomedcentral.com/articles/10.1186/s40545-016-0088-0

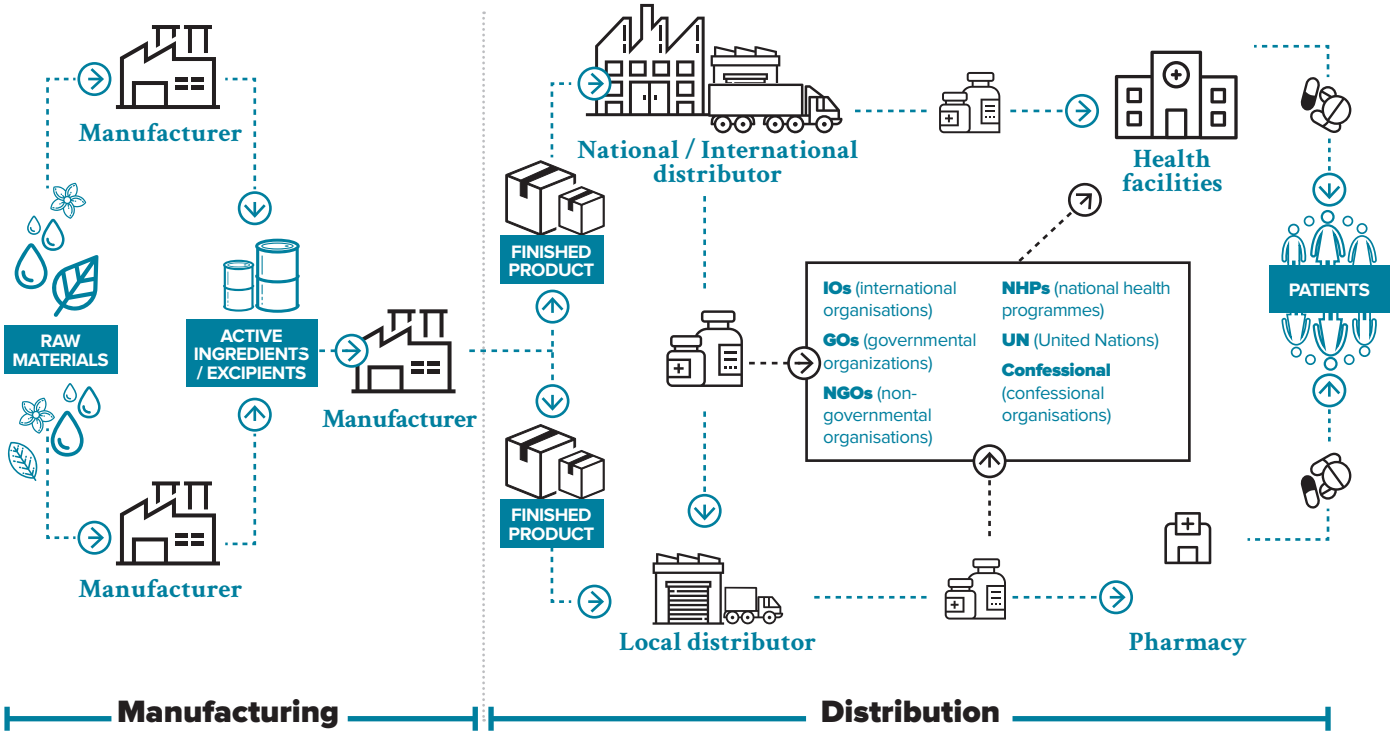
The responsibility of assuring the quality of medicines on the global market is spread among actors with unequal capacity and diverging interests, and the sub-Saharan African market is, in particular, characterised by multiple quality standards, so that a large majority of the population is at risk of receiving poor quality products **(see diagram ⊕ opposite)**. Furthermore, poverty limits access to reliable vendors, and unhealthy price competition fosters the trade of non-quality assured products. Substandard drugs in sub-Saharan Africa are estimated to range from 12% to 48%. But the problem is broader: according to the World Health Organization (WHO), the rate of poor-quality medicines is approximately 10.5% in low- and middle-income countries[1].

Poor-quality medicines include *falsifications*, which are "deliberately or fraudulently misrepresented with regards to their identity, composition or source", and *substandards*, which are "authorised by the NMRA but fail to meet national and/or international standards", due to poor manufacturing and quality control practices that are not detected by regulators[2]. Both falsifications and substandards cause therapeutic failure, toxicity and resistance, leading to human suffering, loss of faith in health systems and waste of resources. But causes and corrective measures are different. Falsifications result from a deliberate willingness to defraud, and they must be fought by repressing illegal manufacturing and distribution. Conversely, substandards result from human error or negligence at manufacturing sites, or from *degradation* due to poor storage and transport conditions; thus, prevention and elimination require a complex set of measures, i.e. strengthening the capacity of NMRAs, of manufacturing and distributors, and promoting ethical behaviour among all stakeholders.

1 ▸ A study on the public health and socioeconomic impact of substandard and falsified medical products: executive summary. Geneva, World Health Organization, 2017

2 ▸ World Health Organisation. Substandard and falsified medical products. 70th World Health Assembly; 2017 22-31 May; Geneva, Switzerland. Available from: http://www.who.int/mediacentre/news/releases/2017/dementia-immunization-refuguees/en/

Supply chain of medicines in low and middle-income countries



Source: A. Nebot Giralt, B. Schiavetti et *al., Quality assurance of medicines supplied to low-income and middle-income countries: poor products in shiny boxes?,* BMJ Glob Heal. 2017

SOME POSITIVE INITIATIVES

The WHO launched in 2001 the Prequalification (PQ) Programme, which had a major impact for ensuring the quality of HIV, malaria and tuberculosis medicines worldwide. The WHO PQ recently designed a *Collaborative Procedure*[3] with NMRAs for the assessment and accelerated national registration of WHO-prequalified products. This enables NMRAs to make use of work already carried out by the WHO and to strengthen their own regulatory oversight processes. Of greatest interest to manufacturers is that application of the procedure enables faster registration in the participating countries. Meanwhile, the WHO Expert Committee on Specifications for Pharmaceutical Preparations makes available technical guidelines to help market players improve their manufacturing, distribution and procurement practices[4]. →

“The WHO launched in 2001 the Prequalification (PQ) Programme, which had a major impact for ensuring the quality of HIV, malaria and tuberculosis medicines worldwide.”

3 ▸ https://extranet.who.int/prequal/content/collaborative-registration-faster-registration
4 ▸ http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1003/en/

> “The launch of the African Medicines Agency (AMA) is expected in 2018, to ensure that all Africans have access to affordable medical products that meet adequate standards.”

At African level, a Medicines Regulatory Harmonisation Initiative was started in 2009 under the New Partnership for Africa's Development (NEPAD); and the launch of the African Medicines Agency (AMA) is expected in 2018, to ensure that all Africans have access to affordable medical products that meet adequate standards. It is hoped that AMA will establish an enabling environment for the development of the pharmaceutical industry, since upscaling access to quality-assured medicines requires both a functioning regulatory framework, and a local pharmaceutical sector able to work according to international standards.

During recent years Quamed[5], a network of non-governmental organisations and local procurement centres, has developed an innovative approach to improve the quality of medicines in sub-Saharan Africa. Quamed members pool resources for auditing distributors and manufacturers according to the WHO standards, in order to orient purchase practices toward quality-assured suppliers. Quamed also increases the knowledge and quality assurance skills of partner organisations through specific training, sharing of information and support. In the future, it hopes to further develop its auditing capacity, in order to build a more direct interaction with manufactures willing to invest in public health needs in Africa.

ADVOCACY AND PEDAGOGY

Awareness of poor-quality medicines remains quite low among non-specialists, i.e. academics, policy makers and actors involved in the supply chain, at least partly because pharmaceutical issues are insufficiently addressed in the study curricula. Thus, more and better advocacy is needed for universal access to quality-assured medicines, targeting regulators, manufacturers and suppliers, international organisations, journalists, purchasers, prescribers, program managers, policy makers, public health actors and patients.

Adequate communication tools, in lay language, are needed to address non-specialists that may play a role in defining policies and/or in advocating universal access to quality-assured medicines. Quamed, for instance, increasingly builds on collaboration with academic institutions, scientific and public health platforms and policy makers, to contribute to documenting the extent of the problem, and promoting universal access to quality-assured medicines[6].

FOCUS
QUAMED

Quamed is an autonomous not for profit association whose objective is to contribute to improving access to quality medicines. It aims to raise awareness about the need to scale up access to quality medicines in resource-poor settings, and to help to reinforce Quality Assurance systems.

5 ▸ Caudron J, Luyckx C, Ravinetto R. Quamed: a North-South collaborative approach toward universal access to quality medicines. In: 60th Meeting of the American Society of Tropical Medicine and Hygiene. Philadelphia; 2011

6 ▸ Nebot Giralt A, Schiavetti B, Meessen B, et al. Quality assurance of medicines supplied to low and middle-income countries: poor products in shiny boxes?. BMJ *Global Health* 2017;2:e000172. (doi:10.1136/bmjgh-2016-000172)

Upgrading and strengthening the regulatory and legislative pharmaceutical framework in sub-Saharan African is of the utmost importance to make quality-assured products available to the most vulnerable populations and to increase health systems' performance. However, a virtuous integration between health policies and local pharmaceutical production is needed to synchronise commercial and health interests. Several existing models can inspire new initiatives or enlarge existing ones. As underlined in a recent UN/WHO joint publication: "(…) this endeavour [ensuring reliable and sustainable manufacturing of medicines] requires a far-sighted vision, the optimal combination of mutually supportive national policies, good governance and rule of law, the establishment of robust national regulatory authorities and other relevant institutions, the availability of diverse technical expertise and access to viable markets. Quality of medicines is non-negotiable and must be assured through the strict application of Good Manufacturing Practices and other quality assurance systems across the pharmaceutical value chain."[7]

"A virtuous integration between health policies and local pharmaceutical production is needed to synchronise commercial and health interests."

The role of the private sector: food for thought

Many manufacturers in sub-Saharan Africa would benefit from technical assistance and technology transfer for upgrading to WHO standards. It is important for the private sector to be able to engage in such collaborative partnerships, for example through public-private partnerships, and as part of corporate social responsibility policy.

Some essential medicines do not currently exist in WHO PQ formulations, e.g.: benzathine penicillin, for mother-to-child transmission prevention of syphilis. The European private sector should be able to invest in these products, either directly or through a local company in sub-Saharan Africa, and through equitable pricing policies.

Specific initiatives may help countries and/or their regulatory authorities to set up sustainable programs in areas that are currently lagging behind, such as Merck for Mothers (for strengthening the supply chain)[8]; and/or to carry out R&D programs for neglected tropical diseases[9].

The private sector plays a key role in setting the price of pharmaceuticals. High prices in poor countries often negatively impact affordability and push desperate patients towards non-secured supply chains. *Ad hoc* mechanisms could be envisaged to systematically improve the affordability of innovator essential medicines in such contexts, such as differential (equity) pricing, or the model of the Patent Pool[10].

7 ▸ Sidibé, M., Yongb, L., & Chan, M. (2014). Commodities for better health in Africa – time to invest locally. *Bulletin of the World Health Organization,* 92, 387–387A
8 ▸ http://msdformothers.com/docs/senegal-informed-push-model.pdf
9 ▸ https://www.dndi.org/diseases-projects/portfolio/fexinidazole/
10 ▸ https://medicinespatentpool.org/

Local production of medicine and accessibility challenges: the example of Pharmivoire Nouvelle

Peter Aouely, *CEO, Pharmivoire Nouvelle*
Nouss Bih, *Head of Investment, Investisseurs & Partenaires*
Elisabeth Kacou, *Chairman, Pharmivoire Nouvelle*

Pharmivoire Nouvelle is a pioneering manufacturer of medical intravenous solutions in Côte d'Ivoire. Its 25 years' experience are proof that locally-based production of pharma products is a realistic, sustainable and viable alternative in terms of accessibility challenges but that it requires public sector support to be able to grow.

FOCUS
PHARMIVOIRE NOUVELLE

Pharmivoire Nouvelle was set up in 1999 by *Coopérative des pharmaciens de Côte d'Ivoire* to provide a missing link in the local health system and pharmaceutical industry and it has become a leading manufacturer of intravenous solutions for Ivorian hospitals and clinics.

Pharmivoire Nouvelle specialises in manufacturing intravenous solutions used in primary healthcare in hospitals for systemic rehydration of patients. Its production facility, located in an industrial park in Abidjan, produces 3 million medical pouches annually for a local market estimated to consume between 15 and 20 million pouches a year.

As is the case for most medicines, the intravenous solutions market is structurally import-based but dependence on imported products has a number of drawbacks: high cost due to high transport costs; long delivery lead times for international orders that negatively impact availability; the costs and problems involved in storing these bulky products; and the risk of counterfeit goods. Faced with insufficient local production, importing has long been the default solution however the efforts of the various different stakeholders need to focus on a gradual shift to local production.

> "Dependence on imported products has a number of drawbacks: high cost [...]; long delivery lead times for international orders [...]; the costs and problems involved in storing these bulky products; and the risk of counterfeit goods."

EMERGENCE OF A LOCAL PLAYER FOR AN ESSENTIAL PRODUCT

Pharmivoire Nouvelle dates from 1999 and the acquisition of the industrial plant of Pharmivoire, a company that had been in operation since 1991. The buyer was Copharm, a pharmacists' cooperative set up in 1993 by *Conseil national des Pharmaciens de Côte d'Ivoire* to help Ivorian pharmacists engage in concerted action and invest in activities that did not previously exist to help complete the country's pharmaceutical industry infrastructure. In its early years, the Company's strategy was based on technical partnerships with South African medical pouch manufacturers who provided technical assistance, upgraded equipment and trained the production team.

But Pharmivoire Nouvelle experienced difficulties from the outset. The plant had been idle for over a year when it was acquired and it was hard to get wholesalers to buy the first production batches. The activity was also negatively impacted by the socio-political crisis in Côte d'Ivoire and in 2008 the Company appointed a new CEO with a mandate to restructure the business and this was duly accomplished. Pharmivoire Nouvelle gradually began to grow and to establish itself as a key player in locally-produced intravenous solutions.

> "Pharmivoire Nouvelle gradually began to grow and to establish itself as a key player in locally-produced intravenous solutions."

THE IMPORTANCE OF LOCAL PRODUCTION

The key advantage of local production is closeness to the market and product availability. The local production facility is capable of making the product available immediately after the quarantine period. Therefore local production is in phase with the need of health clinics to have what is considered an essential medicine constantly in stock and to avoid running out of supplies.

Due to their bulk, wholesale distributors do not like storing large quantities of intravenous solutions. Because they essentially consist of water, they take up a lot of space but only generate very low margins when compared with other medicines. These same characteristics make them expensive to import due to high freight costs which are calculated by weight and volume. Despite these constraints, wholesale distributors must constantly have at least three months' stock on hand to avoid running out.

Local production is only really relevant if it can provide populations with access to quality medicine. The Company's quality strategy is based around the Good Manufacturing Practices (GMPs) which the supervisory body, the DPML applies when it performs its regular – unannounced – inspections. This strict control gives local production a big advantage over imported products whose traceability and reliability is very hard to guarantee. →

THE GROWTH PHASE

In 2011, once the Company had got back on a sound footing, management conducted a major review with the aim of enhancing its production capabilities. The existing production facilities limited annual output to 3 million pouches whereas the local market is estimated at 15-20 million pouches a year.

> “The existing production facilities limited annual output to 3 million pouches whereas the local market is estimated at 15-20 million pouches a year.”

And if the market potential is expanded to include the surrounding region which still imports most of what it needs due to the absence of local players, the total demand is estimated at between 50-100 million pouches a year. Major expected growth in the sector is being buoyed by demographics, increased purchasing power, better access to insurance and better health cover. The recent announcement of universal health cover for Côte d'Ivoire is also driving this positive dynamic.

Seeking to harness this potential, Pharmivoire Nouvelle has drawn up a development plan to upgrade its production facilities, boost its production capacities and ultimately enhance its competitiveness by generating economies of scale. The pharmaceutical sector is very capital intensive and this development project is no exception: it lifts plant production capacity to 12 million pouches a year in exchange for a major investment plan in the order of €9 million. It has been made possible thanks to the support of financial partners like Investisseurs et Partenaires (I&P) and the West African Development Bank (*BOAD*). These stakeholders were attracted by the idea of growing an industry with regional development ambitions that offers a genuine alternative to imported goods in a key sector. For I&P, the prospect of partnering a local player with a clearly structured development strategy, generating major value added and strengthening a local, high-impact pharmaceutical industry were all major deal clinchers.

> “This development project [...] lifts plant production capacity to 12 million pouches a year in exchange for a major investment plan in the order of €9 million.”

POINTERS FOR DEVELOPING LOCALLY-BASED PRODUCTION

Government support is crucial for developing local industry and this should take the form of the public procurement and incentive policies that have been successfully deployed in other countries (i.e., Morocco, Tunisia and Egypt). To take just one example, Morocco, which has become the Continent's second pharmaceutical manufacturer after South Africa, has introduced the principle of national preference into public tenders. This country now has around 40 pharma production facilities that meet 70% of domestic demand and export some of their wares to neighbouring countries.

In terms of public procurement policy, we need to develop arrangements whereby both public and private purchasing agencies give priority to buying from local producers and have recourse to imported solutions only for volumes that cannot be produced locally. A lot is expected of public procurement bodies both in terms of placing reliable orders and making timely payments to businesses that could suffer very negative cash flow impacts if accounts fall long overdue.

Incentive policies need to factor in the features and constraints inherent to the pharma industry. Building and maintaining production facilities is very capital intensive and, unlike other industries, laboratories are subject to very strict marketing authorization controls for new products. However, the incentives available are the exact same as for other industries and this situation needs to be corrected to attract capital into this sector whose importance has been clearly recognised by the various different governments.

> "Government support is crucial for developing local industry and this should take the form of public procurement and incentive policies."

Manufacturers like Pharmivoire Nouvelle are now targeting the regional and not just the national market. To achieve optimal regional integration, this market needs to be made more accessible through more standardised legislation; for example, by introducing a single procedure for obtaining marketing authorisations (MA) that would be valid throughout the Economic Community of West African States (ECOWAS). Similarly, greater clarification is needed of customs requirements for imports used as inputs for manufacturing medicines. While imported medicines are not subject to any tax, customs regulations for certain manufacturing inputs are a very grey area and this discourages local production. Lastly, support for the pharmaceutical sector should be underpinned by measures to upskill the local labour force and this could be achieved by both initial and in-service training throughout the sector. ■

Helping the pharmaceutical industry meet health challenges in Africa

Adrien Absolu, *Health & Social Protection Project Manager, AFD*
Geoffrey Coombs *Investment Officer, Proparco*
Mehdi Tanani, *Senior Investment Officer, Proparco*

With 13% of the world's population and 24% of the global burden of disease – but 6% of health expenditure and only 3% of the world's pharmaceutical output, Africa faces the challenge of access to quality medicines. This challenge is today exacerbated by the development of chronic diseases, which have taken over from the great pandemics of the end of the last century, and the demographic and epidemiological transitions (aging, urbanization) underway across the continent. Over the past three decades, the international community has taken extensive action to provide quality medicines to African populations.

Agence Française de Développement (AFD) and PROPARCO mobilize their respective expertise to improve access to medicines in Africa. AFD supports the regulatory directorates of Ministries of Health in a number of African countries, via grants and technical assistance programs, to assist in the implementation of a coherent institutional framework. It also finances an increase in capacities for the storage and distribution of health products. But while the health sector is a major priority for public authorities, the mobilization and role of private players on the continent is equally essential, in particular throughout the value chain of the drugs economy. PROPARCO, as a private sector development finance institution (DFI), has the objective of supporting private projects that contribute to improving access to quality products, with a focus on supporting all the players in the drug chain, via a customized and innovative range of financing.

> "PROPARCO, as a private sector DFI, has the objective of supporting private projects that contribute to improving access to quality products."

BUILDING SUSTAINABLE PLAYERS: A CENTRAL ISSUE FOR OUR OPERATIONS

African production presents a mixed picture with, on the one hand, "the *pharmerging* countries" – South Africa, Morocco, Kenya and Egypt – where private producers have regional ambitions (Aspen, Ascendis, Cooper Pharma) and, on the other hand, countries with a limited number of small-scale production units, producing generics and parapharmaceutical products and led by individual entrepreneurs and families. As a DFI, PROPARCO makes these SMEs, which have little access to long-term financial resources, central to its operations. They are often companies which have been operating for over ten years and are recognized on their market. Their production activities mainly focus on a limited number of therapeutic ranges: OTC products (anti-inflammatories, wound healing products, antiseptics, dermocosmetics…), prescription products, such as generics, or patent drugs (anti-infective drugs, antibiotics, antimalarial drugs).

The investment projects of the African laboratories we have supported aim to increase production capacities and are sometimes integrated into the development of a new site. One example of this, in Senegal, is the flagship project to relocate the only production site for yellow fever vaccines in Africa to the new city of Diamniadio. It is supported by a EUR 6.5m AFD non-sovereign loan allocated to the Institut Pasteur in Dakar. These investments aim to extend the therapeutic range or introduce modern production lines, which contribute to improving operational efficiency (increase in volumes and reduction in costs, and including an energy efficiency component). What the development projects of these SMEs have in common is that they achieve a threshold effect, which is based on economies of scale and upgrading quality standards. Achieving this threshold effect requires heavy investments and a capacity to control the technical and operational risks brought about by these investments. Supporting these projects requires an appropriate structuring of financing and often strengthening the equity of these SMEs.

“The investment projects of the African laboratories we have supported aim to increase production capacities and are sometimes integrated into the development of a new site.”

ADDRESSING THE CHALLENGES OF QUALITY AND GROWTH

This issue of quality, which is a prerequisite for DFI support, requires the laboratory to implement Good Manufacturing Practices (GMP). This can go as far as a WHO prequalification process, a *sine qua non* condition to be referenced as a supplier to international health product procurement organizations (UNICEF, Global Fund, GAVI Vaccine Alliance). Consequently, the implementation of these standards requires close support from engineering consultancy firms and GMP experts, ideally right from the investment project design phase. →

FOCUS
AFD

Agence Française de Développement (AFD), a public financial institution that implements the policy defined by the French Government, works to combat poverty and promote sustainable development. AFD operates on four continents *via* a network of 75 offices and finances and supports projects that improve living conditions for populations, boost economic growth and protect the planet. In 2015, AFD earmarked EUR 8.3bn to finance projects in developing countries and in French overseas territories. See www.afd.fr

The compliance of a production unit with GMP standards generates an additional cost, which needs to be taken into account in the project investment cost and in future operating costs. DFIs like PROPARCO have technical assistance tools (financing, network of consultants) to support this type of quality approach, for example, in the form of grants to cover part of the GMP audit costs or for capacity building.

Just like the technical risk of the facility's non-compliance with quality standards (GMP, WHO-GMP), the investment project needs to be soundly structured so that it is robust against technical hazards, which generate potential direct additional costs (unexpected increase in ancillary costs for the facility, additional development costs) or indirect costs (delay in completion, leading to a postponement in income generation). The financing of these projects often requires increased efforts in terms of structuring. For example, an investment program may comprise a provision for contingencies to be financed by a standby equity line or standby debt. Partial financing by banking debt must include a capital grace period long enough to cover a period of time comprising the initial construction period and adding a buffer period (up to 50% of the initial period). The capital repayment can be designed to increase in order to follow the ramp-up of the new production unit. These provisions allow the laboratory to get through this critical phase where the debt is increasing, whereas income generation is still based solely on the historical production facilities. We also see that there is a need to strengthen the historical shareholding base of the founders: equity or quasi-equity financing by DFIs or partner investment funds is an increasingly important issue.

> "At the same time as the technical risk of the facility's non-compliance with quality standards, the investment project needs to be soundly structured so that it is robust against technical hazards."

The second thing which the development projects of these laboratories have in common is the visibility and assurance of additional margins or incomes generated by these investments. This is a prerequisite for making these investments and a core factor for their profitability and sustainability. For example, we see that generic manufacturers who extend their therapeutic range with higher added-value products and bank on higher final selling prices and unit margins have made these investments on markets where public authorities were developing incentive mechanisms: bid invitations for public procurement centers requiring a percentage of sourcing from local producers, or setting the final sale price of locally produced medicines with price revision clauses[1] discussed at the time of the marketing authorizations (MA), on the basis of a dialogue between the public authority and manufacturers. As regards manufacturers who make investments to increase capacity, the size of markets is an essential factor, particularly the prospect of growth drivers for export. Access to these markets is facilitated by GMP standards recognized by the supervisory authorities, or is sometimes hampered by a lack of regulatory harmonization at regional level. We thereby see that public procurement, regulatory and taxation policies that are conducive to the local productive base are an essential driver in stimulating private investment.

Another factor which affects the operational sustainability of these laboratories is how they control the growth in their working capital requirements (WCR), alongside the growth in activity. This growth in WCR stems from the increase in the minimum stocks required by

1 ▸ For example, in the event of a significant variation in the cost of inputs.

the public procurement centers and wholesalers/distributors and is, in addition, increased by the long payment periods of these buyers. Consequently, access to WCR financing lines for these African laboratories, the availability of documentary credits for local importers, or exchange risk hedging instruments (often denominated in dollars) are all financing needs for which there are now expectations vis-à-vis traditional financial players or even donors.

INVESTING THROUGHOUT THE VALUE CHAIN?

Working with the private sector with the aim, for DFIs, of improving access to medicines for populations also requires investing in the pharmaceutical distribution sector for two major reasons: quality and price. The quality criteria require the commitment of all players in the supply chain, from production to the last link in distribution. The fragmentation of drug distribution channels in Africa explains extreme situations, where the margin of intermediaries accounts for 90% of the final price paid by the consumer. We consider the consolidation of drug distribution networks as a key factor in economies of scale, allowing the investments required for quality to be made and leading to efficiency gains which can be passed on by a price reduction. For example, PROPARCO has invested in a number of pharmaceutical distribution platforms in Sub-Saharan Africa via commitments in private equity funds active in the region. By supporting this type of company, DFIs contribute to extending the footprint and outreach of well-managed distribution networks, which supply high-quality medicines to consumers at reasonable prices. Goodlife, an East African chain of pharmacies, which also offers diagnosis and telemedicine services, is an example of this. Goodlife has been particularly successful in shortening the supply chain by working as much as possible directly with GMP-certified manufacturers. This sourcing policy has allowed the company to eliminate the additional margin added by intermediaries, which pushes up the retail price, and at the same time guarantees the quality for the final user. PROPARCO is an investor in the LeapFrog Emerging Consumer Fund III, which has recently invested USD 22m in Goodlife. LeapFrog Investments' experienced team is now mobilizing its extensive internal expertise to support the management team in the implementation of an ambitious growth strategy, which will target a network of over 100 stores to reach over 5.5 million consumers by 2020. ■

“The fragmentation of drug distribution channels in Africa explains extreme situations, where the margin of intermediaries accounts for 90% of the final price paid by the consumer.”

FOCUS
PROPARCO

Proparco, the private sector financing arm of Agence Française de Développement (AFD), has been working for development for countries in the South for 40 years. It plays a key role in AFD Group and in French cooperation programmes: financing and support for projects led by companies and financial institutions in developing and emerging countries – from SMEs to regional banking groups, including microfinance institutions.

By **Romain De Oliveira and Fadila Hamdane,** *coordinators of this issue, Executive Editor of PS&D and Senior Investment Officer at Proparco, respectively*

This issue of Private Sector & Development takes a look at a sector with a promising future in Africa: the pharmaceutical industry. While this sector still needs to face a number of challenges on the continent (low level of R&D and local production, fragmentation of distribution channels, development of counterfeit networks, difficulties to access raw materials, etc.), it is, however, driven by State commitments to provide access to healthcare (via the third Sustainable Development Goal) and by the increase in the ability to pay of populations. According to projections and estimates, the continent offers a highly dynamic market with strong growth potential for the *big pharma:* in this magazine, the researchers Nathalie Coutinet and Philippe Abecassis tell us that between 2010 and 2020, Africa's average growth rate is estimated at 10% *(pages 6 to 9)*. Yet this growth covers stages of development that vary from country to country: for example, South Africa and Morocco cover between 70% and 80% of their drug needs, while others import virtually all their drugs.

> "The issue of access to medicines in Africa also concerns quality. Indeed, in certain African countries, it is complicated to establish so-called good manufacturing practices (GMP), which guarantee production quality."

The local production of medicines on the continent is undoubtedly one of the main weak points. Indeed, the overall market largely resorts to imports, which does in fact have several drawbacks: transport related costs inevitably increase the final price of the product, stock procurement is dependent on delivery times, which are sometimes very long and, of course, the risks related to the development of counterfeit products. Yet there are solutions and local players are emerging. This is the case of Pharmivoire Nouvelle, which we give a voice to in this issue *(pages 30 to 33)*: this company from Côte d'Ivoire manufactures intravenous fluids, essential drugs which can be rapidly supplied to hospitals and health centers in the region thanks to their local production unit.

The issue of access to medicines in Africa also concerns quality. Indeed, in certain African countries, it is complicated to establish so-called Good Manufacturing Practices (GMP), which guarantee production quality. In 2010, the Medicines Patent Pool (MPP) was set up, which aims to improve access to effective and high quality treatments for AIDS, hepatitis C and tuberculosis.

To achieve this, *"patent holders have an effective way to share patents on their products in resource-poor settings and may be compensated by royalties. Generic manufacturers are able to produce affordable new medicines more easily and rapidly. Donors and developing country governments are stretching their budgets further to treat more people"*, according to Esteban Burrone and Erika Dueñas *(pages 22 to 25)*, who are both from the Medicines Patent Pool organization.

In our view, to remove the persistent obstacles, it is essential to build synergies, at various levels, between private sector players and public decision-makers. Innovative solutions and tools are emerging and we talk about them in this issue. Adrien Absolu and Mehdi Tanani, the coordinators of this issue, remind us that the question of development finance institutions (DFIs), which include Proparco, financing private players is obviously crucial *(pages 34 to 37)*. ■

PS&D

Since 2009, Proparco has coordinated the Private Sector & Development (PS&D) initiative, examining the role of the private sector in southern countries.

Issued as a quarterly themed magazine and specialist blog, the PS&D initiative presents the ideas and experiences of researchers and actors in the private sector who are bringing true added value to the development of the countries.

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