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South Africa, Ghana and Kenya: Strengthening the pharmaceutical sector in Sub-Saharan Africa with the contribution of *Sistema Italia*

Position Paper

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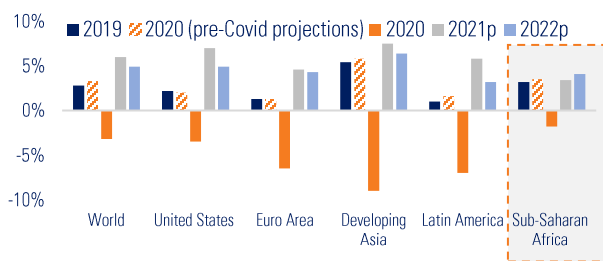


The European House
Ambrosetti



The context

The Covid-19 pandemic had a two-fold impact on all geographical areas around the world: on the **healthcare sector**, with confirmed cases and deaths increasing exponentially over time, and on **economic growth** with every region experiencing a severe contraction in GDP. Against the projected global growth of +3.3% calculated in January 2020, an average GDP decline of -3.2% was registered globally. Similarly, **Sub-Saharan Africa** experienced its **first economic recession** in over twenty-five years with **-1.8% GDP**. Over 2021-2022, the world economy is projected to rebound, with Sub-Saharan Africa coming back into line with the previous growth trend (+3.4% in 2021 and +4.1% in 2022).



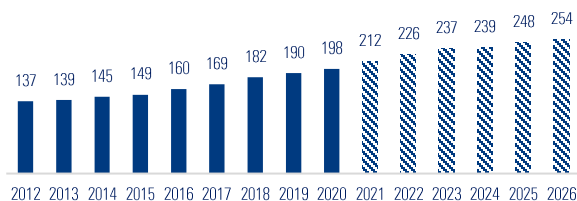
GDP growth in world regions vs. pre-pandemic projections for 2020 (calculated in January 2020), (% change), 2019-2022p. Source: The European House – Ambrosetti based on International Monetary Fund data, 2021.

As soon as the pandemic broke out, drug stores and medical warehouses ran out of stocks, making it hard to fill drug and treatment prescriptions, while healthcare systems collapsed. In fact, Covid-19 has taught us some important lessons:

- 1. Health and healthcare are at the basis of solid economic growth and broader socio-economic development**, as was highlighted at the G20 Leaders’ Summit in Rome.
- 2. An efficient healthcare system and a thriving pharmaceutical sector are necessary for resilience at national level**, and have now become the center of every national and international agenda.
- 3. Partnerships between public and private actors are key** to enable investment, research, and overall development of strong value chains throughout the pharmaceutical sector.

In this unprecedented context, to overcome the Covid-19 crisis, **research** in the pharmaceutical industry has been strengthened, leading to the discovery of new treatments, drugs and vaccines in record time. Governments have channeled public investment towards the development of Covid-19 vaccines thanks to flourishing biotech and pharmaceutical sectors and **record R&D investments worth \$188 billion in 2020**. In fact, pharmaceuticals and biotechnology have the highest intensity of R&D investment to sales. As a result, **extraordinary innovations** in the medical sector could be developed at exceptional speed, whose application is not limited to Covid-19, but will be relevant to other uses in the future:

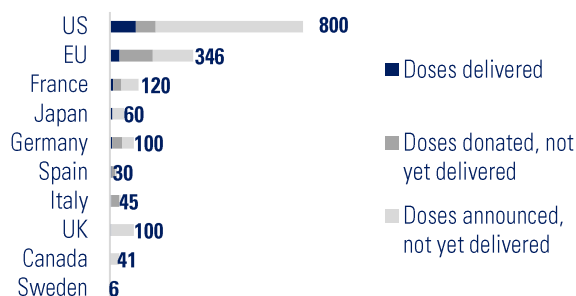
- In less than nine months, **vaccines with mRNA technology** against Covid-19 have been developed and manufactured. The process has been facilitated by previous research that envisioned their use on other infectious diseases such as the flu, Zika virus, rabies and cytomegalovirus. Thanks to their adaptability, mRNA vaccines are currently under study for ensuring protection against multiple respiratory diseases with a single shot. In addition, research is ongoing for application in immunotherapy against tumoral cells thanks to the systemic effect of vaccination able to reach all organs of the body.
- **Digital health** has been applied to contact tracing, testing and surveillance. Thanks to data-driven technologies, telemedicine and ad hoc apps played an important role in supporting healthcare.
- **Artificial intelligence** has been essential for a range of activities, from diagnosis acceleration to genome sequencing and research analysis. A total of 6,657 research papers have been published worldwide on AI and medicine, registering +42% in 2020 compared to 2019.



R&D investments in pharmaceuticals and biotechnology (billion \$), 2012-2026. Source: The European House – Ambrosetti based on EFPIA and EvaluatePharma data, 2021.



At the same time, the Covid-19 crisis has revived the need for **international cooperation**. According to a United Nations survey, 87% of respondents believe global cooperation is vital to deal with current challenges and that the pandemic made international cooperation even more urgent. With this spirit, the UN-backed COVAX Facility aimed to make two billion doses of Covid-19 vaccine available by the end of 2021, including at least 1.3 billion doses to lower-income economies. However, there is still a significant gap between the announced donations of vaccines and actual deliveries to developing countries. Of the total announced donations by the top donor countries, **only 15% has actually been delivered to developing countries**, corresponding to a total of 200 million deliveries out of the 1.6 billion promised doses.



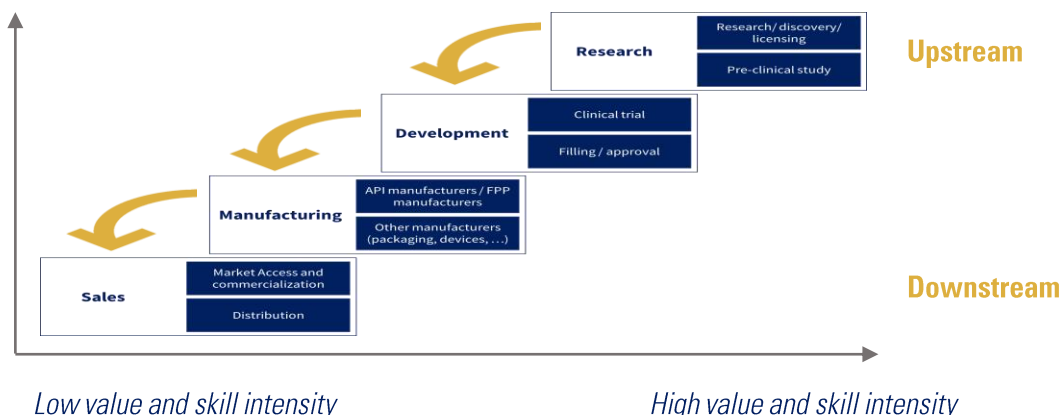
Covid-19 vaccine doses (delivered, donated and announced) to the COVAX facility by top 10 donor countries, (absolute number in million), 2021. Source: The European House – Ambrosetti based on Our World in Data, 2021.

The pharmaceutical sector in Africa

The value chain along the pharmaceutical sector is characterized by phases with **varying degrees of value and skill intensity**.

The global pharmaceutical market is expected to be worth \$1.4 trillion by 2020, representing a 4.2% compound annual growth rate (CAGR). Sub-Saharan Africa is expected to lead the trajectory at a rate of 7.5% CAGR. It is, in fact, among the fastest-growing markets in the world: starting from a base of \$4.7 billion in 2003, it is estimated to be worth about **\$50 billion in 2020**. This progress is the result of a number of interconnected trends. On the one hand, the **urbanization rate** has risen from 13% in 1965 to 44% in 2020. On the other, from a **demographic point of view**, population growth—with estimates of doubling population by 2050, gradual aging and higher life expectancy, reaching 61 years old—have transformed existing trends in healthcare. As a matter of fact, today Africa experiences a greater incidence of **non communicable diseases** (NCDs), such as cancer, diabetes and cardiovascular diseases. The World Health Organization (WHO) predicts that NDCs in Africa will increase by 21% by 2030, when they will surpass the percentage of infectious diseases. Demographic trends and changes in lifestyle are therefore **pushing up the healthcare demand**, including for pharmaceutical products and treatments.

Nevertheless, **the growth in the pharmaceutical market has not been matched by a corresponding increase in local manufacturing capacity**. To address the increasing disease burden, Sub-Saharan African countries remain import-dependent for the supply of essential medicines where **90% of drugs and 99% of vaccines are imported**. Of those, it is estimated that 60% come from Europe, 12% from India, 9% from China and 16% from other regions. Only 3% of pharmaceutical imports originate from within Africa. Indeed, even in countries with an existing pharmaceutical manufacturing sector, **the share of local production capacity remains negligible**, ranging between 10 and 30%.



The pharmaceutical value chain.

Source: The European House – Ambrosetti, 2021.



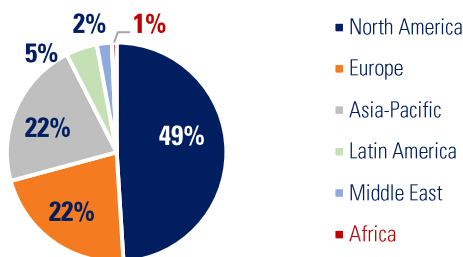
The pharmaceutical sector in Sub-Saharan Africa is still **underdeveloped**, especially with respect to the demand of its 1.3 billion inhabitants. In comparison with other developing countries, the share of global revenues remains well below 1% in Sub-Saharan Africa, while it is around 3% in India, 10% in China and 3% in countries within the Association of South-East Asian Nations (ASEAN). Similarly, global exports account for less than 1% while India, China and ASEAN countries register 1%, 6% and 2%, respectively.

Less than 500 pharmaceutical companies are active in the African continent, against over 10,500 in India, 5,000 in China and 1,600 in ASEAN countries. The majority of companies are concentrated in North Africa, while Sub-Saharan African manufacturers are mostly **small privately-owned firms** that serve national markets. However, there are also some cases of publicly-listed companies (e.g., Dannex in Ghana and CiplaQCIL in Uganda). Over recent decades, African manufactures have been owned, in full or in part, by foreign firms. Some companies have invested in facilities using international equity finance (e.g., Universal Corporation Ltd. in Kenya).

The leading **pharmaceutical multinational companies** in the world are present in African countries, mainly with activities connected to market access and distribution. Among the top pharmaceutical companies that make up over 40% of global pharmaceutical production value, only five (Johnson & Johnson, Merck, Pfizer, Sanofi and GSK) have manufacturing activities in Sub-Saharan Africa, mostly concentrated in South Africa.

Efforts towards **local manufacturing** are concentrated on **generic drugs**, which are rapidly gaining an important market share. Sub-Saharan African manufacturers mostly produce a limited range of products, restricted to over-the-counter formulations and basic prescription drugs covering, among others, cough preparations, vitamins, analgesics, basic sedatives, anti-malarial, anti-helminthic, older generation antibiotics, anti-diabetics, etc. Many of these are produced in simple dosage forms, such as plain tablets, capsules, lotions and suspensions. There are some examples of local companies producing more advanced formulations, such as sustained release tablets and complex products, such as immune sera and immunoglobulins, sterile products and vaccines.

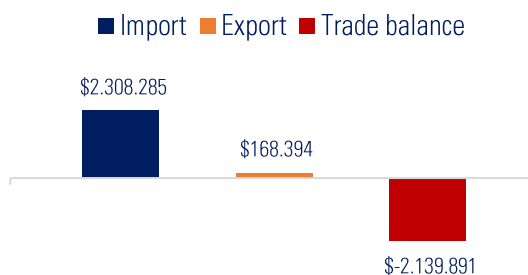
As a result, the **African pharmaceutical market** makes only a small contribution to the global pharmaceutical market. It accounts **for just 0.6% of the total**, which is estimated to be worth \$1.4 trillion in 2020. North America dominates the market with almost half of all activity, followed by Europe and the Asia-Pacific region.



Share of global pharmaceutical market by region(%), 2020. Source: The European House – Ambrosetti based on UNCTAD data, 2021.

African pharmaceutical manufacturers mainly import **active pharmaceutical ingredients** (APIs) and excipients, especially from India and China, together with plant equipment and machinery. Analytical equipment, on the other hand, is typically obtained from Europe. At the same time, a large share of the drug supply, especially for HIV/AIDS, malaria and tuberculosis is provided by international agencies at a level that will not be sustainable in the long term.

Therefore, the **over-reliance on imports of pharmaceutical products had a negative impact on the trade balance of \$2.1 billion** in 2020. In comparison, China has a \$2.7 billion positive trade balance of pharmaceutical products, while India and ASEAN countries have negative balances of \$471 million and \$52 million, respectively.

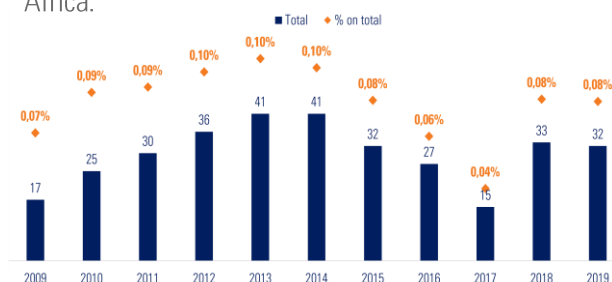


Import, export and trade balance in pharmaceutical products in Sub-Saharan Africa ('000 US\$), 2020. Source: The European House – Ambrosetti based on UNCTAD data, 2021.



The development of a strong, independent pharmaceutical manufacturing capacity is only possible in a context of cutting-edge activities in research and development. **Less than 0.4% of gross domestic product is allocated to R&D in Sub-Saharan Africa**, against a global average of 1.7%. Likewise, the regional situation regarding the presence of full-time researchers also shows a wide disparity. Globally, the number of researchers per million inhabitants stands at 1,198, but it is as low as 99 in Sub-Saharan Africa. As a result, the R&D contribution is irrelevant compared to the rest of the world, with only 32 patents grants in pharmaceutical research in Sub-Saharan Africa in 2019, 24 of those in South Africa.

Within this framework, the African Union promoted **The Pharmaceutical Manufacturing Plan for Africa** and launched the **Africa Medical Supplies Platform** to harmonize regulatory frameworks and strengthen the procurement and supply chain management system by developing pooled procurement as an innovative mechanism to incentivize local manufacturing. As a result, prices will decrease thanks to higher production volumes, making Africa able to compete through significant economies of scale in healthcare. As a consequence, Africa will **attract pharmaceutical manufacturers** to build plants locally and partner with local manufacturers, thus enabling investment in training and skills, technology transfer agreements and employment opportunities, both directly and through the development of supporting and related industries. Overall, it is estimated that AfCFTA will increase intra-African trade of pharmaceuticals, with a potential reduction of at least 25% of imports within two years and cheaper costs of pharmaceutical products by at least 30% within three years.



Total patent grants in pharmaceuticals in Sub-Saharan Africa (absolute value) and share of world total (%), 2009-2019. Source: The European House – Ambrosetti elaboration on World Intellectual Property Organization data, 2021.

Another important factor that has been hindering prospects for growth in the pharmaceutical sector in Sub-Saharan Africa is the **fragmentation of its small markets**, which cannot compete with their Asian counterparts that operate in vastly larger markets and therefore enjoy economies of scale. However, projections of market integration in Africa will be aided by the implementation of the **African Continental Free Trade Area (AfCFTA)**, the largest free trade area in the world. It aims at boosting intra-African trade by providing a comprehensive and mutually beneficial trade agreement among the member states, covering trade in goods, services, investment, intellectual property rights and competition policy. Through a sectoral approach, AfCFTA provides opportunities for capacity enhancement in the pharmaceuticals area by improving collaboration and reducing barriers to movement of goods, services and people.

The relevance of manufacturing capacity has also been highlighted at European level. Within the context of the G20 Global Health Summit in Rome, the **European Union** announced the mobilization of **€1 billion** for the Team Europe Initiative on manufacturing and access to vaccines, drugs and health technologies in Africa. Funding will come from the EU budget, European Investment Bank, EU member states and EU development banks. The project aims at supporting an enabling environment for local vaccine manufacturing in Africa and tackling barriers involving both supply and demand. On the supply side, together with the EIB and development banks, it will incentivize and de-risk investment in local pharmaceutical and biotech companies, for example through a coordination platform for European development banks to facilitate investment in the health sector in Africa. On the demand side, it will work with African leaders and communities to tackle the fragmentation of local markets and help consolidate demand, facilitate market integration and the use of locally-produced goods. As an overall objective, the Team Europe Initiative plans to set up **regional manufacturing hubs**, focusing on countries with the highest potential. Among the candidates on the list are Ghana, Kenya and South Africa.

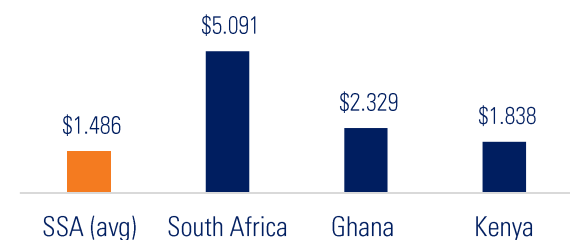


Country focus

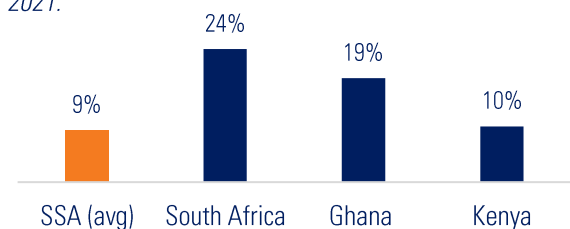
From the perspective of developing a pharmaceutical hub at an African level, it is imperative that the entire geographical area of the continent be covered. Within this context, three countries have been selected by The European House – Ambrosetti in collaboration with the Italian Trade Agency: South Africa, Ghana and Kenya, which would cover Southern, Western and Eastern Africa, respectively. Selection was also based on the **Health and Healthcare Framework in Africa** provided by WHO and their ranking within their corresponding regions. The normalized index analyzes five aspects:

- healthcare expenditure per capita;
- investment indicator, in terms of the health workforce, products and infrastructure;
- performance indicator in terms of access, quality, demand and resilience;
- outcome indicator in terms of service availability, coverage and responsiveness, and financial risk protection;
- healthy life expectancy in years.

Furthermore, South Africa, Ghana and Kenya are ideal candidates thanks to a **fertile and productive socio-economic environment**, where, for instance, GDP per capita and tertiary education rate is higher than the Sub-Saharan Africa average.



GDP per capita (current US\$), 2019. Source: The European House – Ambrosetti based on World Bank data, 2021.



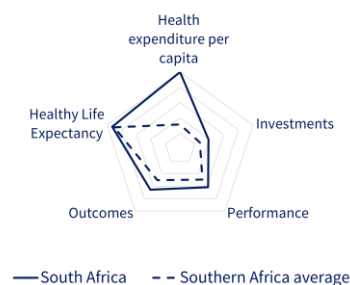
School enrollment in tertiary level (% gross), 2019.

Source: The European House – Ambrosetti based on World Bank data, 2021.

South Africa

21. According to the Index on State of Health, South Africa is among the **best performers** in Southern Africa and in Africa, especially in terms of healthcare expenditure, investments, performance and health-related outcomes. These achievements ensure a vibrant basis for future healthcare and pharmaceutical developments.

Health and Healthcare Framework, South Africa vs regional average (normalized, 0-1), 2018. Source: The European House – Ambrosetti based on WHO data, 2021.



South Africa is the **leader in the pharmaceutical industry**, accounting for about 80% of total production on the African continent. The market is valued **at \$5.2 billion**, making it the biggest in Africa (ahead of Nigeria, Egypt and Kenya). Under the Department of Health and the South African Health Products Regulatory Authority, **over 275 companies** are licensed to manufacture, import, export and distribute pharmaceuticals.

Among those, Aspen Pharmacare is one of the top ten largest generic manufacturers in the world with 12% of market share, with a size comparable to leading international generic manufacturers.

Investment in R&D is estimated at over \$66 million for upcoming and ongoing trials. The internal manufacturing capacity currently satisfies 27% of domestic demand. It is mostly concentrated on **generics** with evidence of advancements in **APIs** for antiretrovirals (ARVs), the first of its kind on the continent. To address this matter, in its Industrial Policy Action Plan (IPAP), the South African government designated the pharmaceutical industry as a priority sector with specific measures to increase local production of pharmaceuticals.





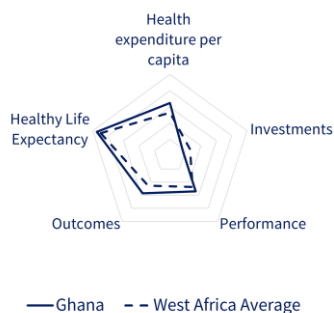
South Africa was at the forefront in the fight against Covid-19. Over recent months, manufacturing activity has been ramped up thanks to partnerships with international, regional and national actors.

- A deal between Aspen Pharmacare and Johnson & Johnson made South Africa the continent’s first major manufacturing base for fill-finish process of Covid-19 vaccines at the site in Gqeberha, Eastern Cape. Currently, it delivers 250 million doses annually of the final packaged versions of the Johnson & Johnson vaccine and, of those, 31 million are destined for South Africa whereas the rest are destined for other African countries thanks to an agreement with the African Union. Recent announcements confirm that it will be intensifying its manufacturing capacity to 1.3 billion doses a year by 2024.
- In 2021, a Covid-19 vaccine manufacturing consortium was agreed upon among the Medicines Patent Pool (MPP), the World Health Organization (WHO), Afrigen Biologics (PTY) Limited, the Biologicals and Vaccines Institute of Southern Africa (Biovac), the South African Medical Research Council (SAMRC) and Africa Centres for Disease Control and Prevention (Africa CDC). Through a shared responsibility approach, the partners will ensure that the most suitable platform technologies are selected, that technology transfer is in place and that funding is secured for the hub, clinical studies and manufacturing support.

Ghana

Ghana’s achievements in the Index on State of Health are outstanding in terms of performance and outcomes related to healthcare services. Instead, it slightly underperforms compared to its peers in West Africa with scope for greater promotion in health investments.

Health and Healthcare Framework, Ghana vs regional average (normalized, 0-1), 2018. Source: The European House – Ambrosetti based on WHO data, 2021.



Today, Ghana has a thriving pharmaceutical sector, with an estimated market value of **\$600 million** in 2020 and an estimated annual growth rate of **13.9%**. More than 70% of the total market is made up of prescription drugs, primarily sourced from foreign inputs and finished pharmaceutical products from India, China, Belgium, Switzerland and the United Kingdom. The remaining 30% comprises **over-the-counter drugs, which are generally provided by local manufacturers**. Only one-third of the pharmaceutical companies are actively involved in simple prescription formulation.

The major local manufacturers include Letap, Ayrton Drug Manufacturing, Phyto-Riker, Amponsah Efah, Kinapharma, Danadams and Pharmanova. None of these local manufacturing plants is compliant with World Health Organization (WHO) good manufacturing practice (GMP), and currently manufacture mostly simple products. Some local firms, for example Kama and Ernest Chemists, are involved in both manufacturing and importing. Only one company, LaGray, manufactures an API for local consumption.

In recent years, the **Ghanaian government has taken some decisive steps to promote and encourage the local pharmaceutical industry:**

- a **restricted imports list** to ban imports of finished formulations of 40+ widely-used products that could be produced locally, including ampicillin, paracetamol and aspirin;
- a **10% import duty** on finished formulations to ensure a larger market for local manufacturers;
- a **15% price preference** for local manufacturers in public procurement, although this mechanism is experiencing some difficulties in its implementation, and improvement in its consistency and transparency may be needed.

Overall, local manufacturers in Ghana still face major challenges, including higher costs of production and absence of manufacturing facilities compliant with WHO good manufacturing practice (GMP). Factors resulting in the relatively higher cost of production in Ghana include the inflated cost of raw materials, utilities, transportation, equipment maintenance, financing and technical capacity. To address this issue, Ghana is the **first country in which the AU Pharmaceutical Manufacturing Plan for Africa is being implemented**.





It has received technical support and capacity building from developed countries in upgrading local manufacturing to WHO GMP standards. As part of this plan, the United Nations Industrial Development Organization has arranged for visits of technical experts from developed countries to provide advice and training for upgrading local manufacturing to WHO GMP standards. In addition, the Food and Drugs Authority of Ghana is also prioritizing the technical upgrade of local manufacturers. An industrial support department has been established to liaise with firms and provide necessary technical inputs.

To attract an increasing number of investors, a new facility is under construction. The Pharma-Industry Park is a \$320 billion project within the Dawa Industrial Zone (DIZ). Its aim is to ensure that between 60% and 80% of drugs are produced locally.

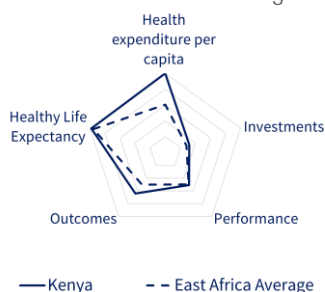
Ghana has already received **international attention**. The German pharmaceutical company Merck signed a Memorandum of Understanding (MoU) with local companies in Ghana for a vaccine manufacturing plan that comprises basic design, facility construction and equipment supply installation, technological transfer, validation support and training, as well as qualification support. After a feasibility study, a contract is expected to be signed within the next five years for a volume of €25 million. In addition, the Government of Ghana signed a public-private partnership with Novartis to improve the diagnosis and accelerate treatment for people with sickle cell disease.

Kenya

The health sector in Kenya has experienced remarkable development in recent years, with efforts being made in controlling diseases such as malaria, TB and cholera, while actively fighting the HIV pandemic. As a result, Kenya serves as a medical tourism destination for visitors from neighboring East African countries. With high healthcare expenditure per capita and over 8% of GDP represented by health expenditure, Kenya provides a solid healthcare sector with outcomes higher than the East African average.

Health and Healthcare Framework, Kenya vs regional average

(normalized, 0-1), 2018. Source: The European House – Ambrosetti based on WHO data, 2021.



With a market value of over \$1.2 billion, the pharmaceutical industry in Kenya is growing at a rapid pace and offers excellent opportunities for exporters and manufacturers to establish their products and services in the East Africa pharmaceuticals market. Kenya is currently the **leading producer of pharmaceutical products in the Common Market for Eastern and Southern Africa (COMESA)** region, supplying about 50% of the market in those regions. Kenya’s prescription pharmaceuticals market accounts for around 75%, but the fastest growth in the coming years is expected in over-the-counter product sales.

The number of companies engaged in manufacturing and distribution of pharmaceutical products in Kenya continues to expand, driven by the government’s efforts to promote local and foreign investment in the sector. There are more than 35 manufacturing units, which mainly provide generic drugs. Consequently, local pharmaceutical manufacturing in Kenya supplies approximately one-quarter of the internal demand.

Like most developing countries, Kenya is facing a double burden of communicable and non-communicable diseases. **Healthcare demand is shifting towards non-communicable diseases**. Cardiovascular is Kenya’s dominant and fastest-growing prescription market segment, worth around \$40 million and showing a CAGR of 15.4% over the last decade, while the diabetes market was valued at \$35.2 million last year with a CAGR of 13.5%.

The market is heavily dependent on a private clientele, and affordability remains a primary restraint, together with low reimbursement rates. Kenya also enjoys preferential access to the regional market under a number of special access and duty reduction programs related to the East African Community (EAC) and the Common Market for Eastern and Southern Africa (COMESA), among others.

In addition, Kenya also has a **growing medical devices industry**, with an estimated market of \$130 million. Most medical devices are imported, with domestic production focused on basic consumable items and personal protective equipment (PPE) following the Covid-19 pandemic. To further support this market, exemption of medical equipment and apparatus from VAT is included in the 2019/20 budget. These exemptions will support strong medical device market growth and is expected to register double-digit increases annually between 2019 and 2024.





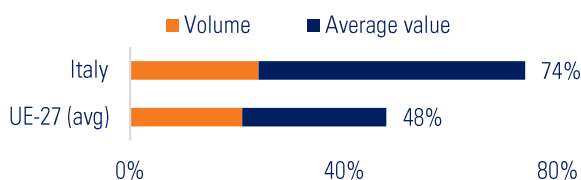
Kenya provides a stable and encouraging political environment, making it an **investor-friendly country**. Furthermore, Kenya offers a constant supply of a well-trained labor force that is capable of handling all types of pharmaceutical industry operations. As a member of the World Intellectual Property Organization, trademark and patent protection is guaranteed. The recent enactment of the **Special Economic Zones Act (2015-SEZA)** presents an opportunity to invest in manufacturing plants for medical supplies to the region. However, a main obstacle for manufacturing lies in a **complex regulatory environment**, mostly in the procurement and supply sectors, due to the overlapping work of government initiatives, aid agencies and NGOs.

Policies that create incentives for extending and deepening technological capabilities are critically important if the local industry is to transition towards a high growth technological trajectory. This could be achieved through **greater collaboration between foreign-owned pharmaceutical firms and locally-owned ones** can contribute to knowledge intensification in the local industry.

The contribution of *Sistema Italia*

Italy offers one of the most thriving life sciences ecosystems, thanks to an environment that supports innovation, research and digitalization. Thanks to—or because of—the Covid-19 pandemic, the importance of the life sciences ecosystem has been underscored, with respect to pharmaceutical products and medical devices. Today more than ever, life sciences have gained a renewed, dual strategic relevance in the health system as well as in the economic system. While satisfying the public’s health demands, the industry also involves other economic activities, thus representing an investment for the resilience of entire countries.

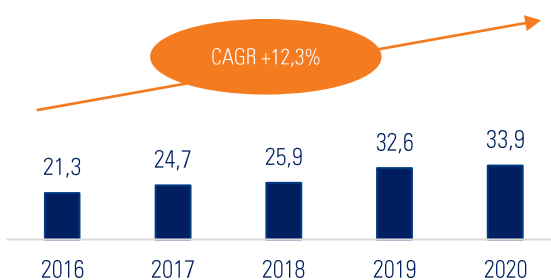
In Italy, the pharmaceutical sector is a driving force for growth and development. The total value of **pharmaceutical production reached €34.3 billion** in 2020, an increase of 6.5% compared to 2018. This result is driven almost entirely by the evolution of exports, which amounted to €33.9 billion in 2020. **Exports registered a five-year growth of +74%**, a higher rate compared to the European average (+48%), thanks to an increase in the average value of exported products, reflecting its highly innovative content.



Evolution of pharmaceutical exports between 2015 and 2020 in Italy and EU -27 (% change), 2015-2020.

Source: The European House – Ambrosetti elaboration of Farmindustria data, 2021.

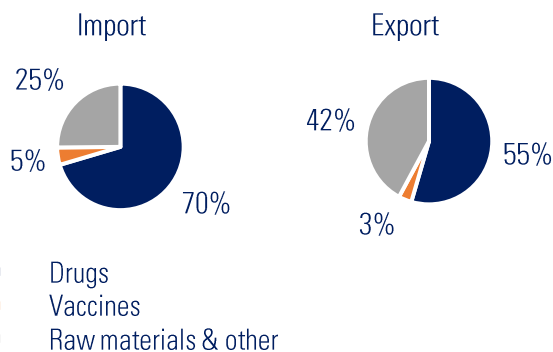
In fact, Italy has been **exporting over 85% of its pharmaceutical production** over the last five years. These results make Italy a leader in Europe and in the world thanks to its capacity to combine high levels of innovation, investment and added-value production.



Value of pharmaceutical exports (billion €), 2016-2020.

The European House – Ambrosetti “Meridiano Sanità”, 2021.

In a more detailed analysis of exports, drugs prevail, accounting for 55% of exports and 70% of imports. Basic substances and other products account for 42% of exports and 25% of imports. Finally, vaccines represent 3% of exports and 5% of imports.

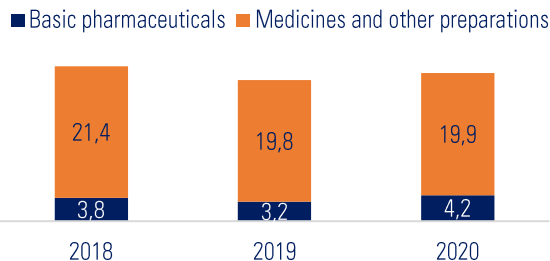


Trade decomposition by category in Italy (% on total), 2020.

Source: The European House – Ambrosetti elaboration of Farmindustria data, 2021.

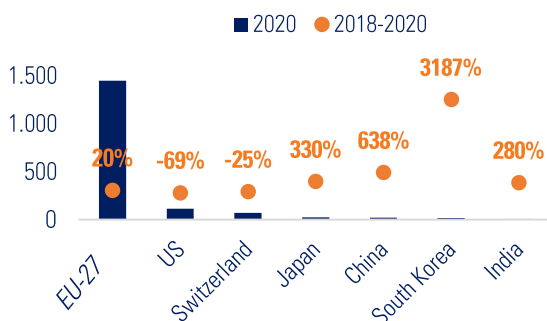


Looking at the current **trade relations in the pharmaceutical sector between Italy and Africa**, while the volume of drugs and other preparations is almost stable at around €20 million, the **export of basic pharmaceuticals increased by 11%** over the last two years.



Value of pharmaceutical exports from Italy to Africa (euros), 2018-2020. Source: The European House – Ambrosetti based on ISTAT data, 2021.

At the same time, **Italy is also reliant on imports, especially for drugs and other pharmaceutical preparations.** Its main import partners are the European Union, the United States, Switzerland, Japan, China, South Korea and India. Interestingly, while the European Union remains the most important import partner with over €1.4 billion worth of imports, over the last two years, Asian countries played an important role, registering +3187% imports from South Korea, +638% from China and +280% from India.



Italian imports of drugs and other preparations and its evolution between 2018 and 2020 (billion € and % change), 2018-2020. Source: The European House – Ambrosetti based on ISTAT data, 2021.

Overall, what emerges from these trends is a **gradual rebalance of trade markets**, where Italy and Africa can build a win-win partnership. On one hand, Italy can increase its exports towards Africa for pharmaceuticals, especially those with high added value. On the other hand, Africa can become a source

of generics for Italy, once pharmaceutical manufacturing hubs are in place.

Pharmaceutical research represents the largest investment in R&D in the world and **between 2020 and 2026, companies are expected to invest around \$1.500 billion**, 80% of which will be allocated to Open Innovation networks made up of different players (companies, public entities, start-ups, industrial parks, clinical centers). This represents a great opportunity for Italy, where total investment in the pharmaceutical industry amounts to €3 billion, almost equally distributed between production plants and R&D. In fact, the Italian pharmaceutical sector is increasingly committed to research, ranking fourth in Europe after Switzerland, Germany and France. In 2020, pharmaceutical companies invested **€1.6 billion in R&D**, which corresponds to 6% of total investment in the country. From 2015 to 2020, R&D investment has grown by **14%** that has made possible research advancements in the fields of biotech, vaccines, plasma-derived products and advanced therapies.

Investment has also led to an increase in **patents** for pharmaceuticals and biotechnology submitted to the European Patent Office by companies in Italy: +29% in 2020, higher than the European average (+10%).

Italy also plays an important role in **clinical trials**: the pharmaceutical industry annually invests more than €700 million. Investing in clinical trials means making innovative therapies available to patients and offering opportunities for professional growth to researchers, thus increasing scientific competitiveness.

Italy also benefits from other strengths, making it among the best performers, including:

- **No. 1 industry in investments in Open Innovation per employee;**
- **No. 1 industry by share of companies with collaboration agreements with universities and public research centers, 80% of the total;**
- Among the highest productivity among industrial sectors in terms of **value added per employee** (+123% compared to manufacturing);
- Internationalization rate, being the **no. 1 industry by share of companies with foreign capital**, which contribute 57% to the value of the sector.





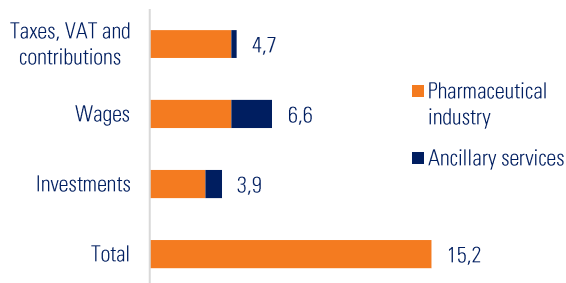
Overall, the pharmaceutical sector enables positive multipliers of economic activity:

- **For every euro of added value generated directly, €1.7 additional are activated** in the entire economy;
- **For every person employed in Italy, 3.5 additional jobs are created** in the economy.

Complementary to the pharmaceutical industry, the **medical devices industry** is increasingly relevant in the life sciences ecosystem in Italy. It is a very heterogeneous, highly innovative and specialized industry with a market worth **€16.7 billion**, with Imports and exports on the rise. In 2020, exports reached €5.7 billion, up +7.9% compared to 2019. The main destination markets include the United States, France and Germany. Looking at imports, they also increased by 5.5% with a value of over €8 billion. In this segment, small companies coexist with large groups for a total of more than 4,000 companies, employing 94,000 employees throughout Italy.

The process towards the development of medical devices, from basic research to the finished output, requires major investment. In 2020, R&D investment amounted to €934 million, the majority of which going to experimental development.

Overall, the life sciences ecosystem in Italy creates a network of international and highly innovative excellence, which contributes to the **socio-economic development of the territories where companies operate**, particularly in terms of employment and added value. In fact, ancillary sectors (packaging, machinery, specialized construction, engineering services and utilities) employ more than 225,000 people and generate an additional €20 billion.



Direct and indirect contribution of the pharmaceutical industry in Italy, (billion €), 2020. Source: *The European House – Ambrosetti elaboration of Farmindustria data, 2021.*

Even though the presence of the life sciences sector is concentrated in five regions (Lombardy, Lazio, Tuscany, Emilia Romagna and Veneto), **production plants and research centers are present across Italy**. This network system enables a vast circulation of direct and indirect benefits from the pharmaceutical chain.



Location of production (left) and research (right) centers of pharmaceutical companies in Italy, 2021.

Source: *The European House – Ambrosetti “Meridiano Sanità”, 2021.*

Strategic insights for the development of pharmaceutical supply chains in Sub-Saharan Africa and perspectives for cooperation with Italian players

The paragraphs above have illustrated the state of the pharmaceutical supply chain in Sub-Saharan Africa from both a national and regional standpoint. At each level, there are both great opportunities for development and an urgent **need to address major criticalities to strengthen production capacity towards greater autonomy**. This urgency has become even more evident with the Covid-19 crisis and its consequences in the field of health and health crisis management.

As seen, the Covid-19 crisis has demonstrated the close relationship between health and socio-economic well-being, along with the importance of public-private partnerships on a national, regional and global scale. In fact, the pandemic has **put supply chains in jeopardy, not only in Sub-Saharan Africa, but also in the EU and in many countries on a global scale**. There is, therefore, a need to plan a reorganization of supply chains and to reshape value chains on an international and national level to achieve **greater independence and resilience** in the face of current and future crises.



The development of a national and regional pharmaceutical industry contributes to building more effective and sustainable healthcare services. It also positively affects the country's trade balance, growth, competitiveness, attractiveness and bargaining power, as well as the capability of governments and healthcare systems to provide an effective answer to local specific healthcare needs. A stronger local pharmaceutical industry also improves a country's ability to address local priorities and creates tangible and intangible links between industry and research. Positive effects are amplified if countries are able to cooperate and develop synergies at **regional and supra-regional levels**. In Sub-Saharan Africa, regional initiatives that can be leveraged include the ECOWAS Regional Pharmaceutical Plan and the EAC Regional Pharmaceutical Manufacturing Plan of Action which are adequately leveraged together with the African Continental Free Trade Area.

Links between pharmaceutical industry and healthcare systems in Africa

1. Increased national government commitment to **medicine funding and access**
2. Increase **pharmaceutical skills and training**
3. More **effective procurement** from public and no-profit thanks to close-to-market suppliers
4. Improved **rural access** to medicines thanks to more effective domestic distribution networks
5. Competitive **falling costs and prices** of medicines
6. Faster and more effective **response to local healthcare needs** (supply shortages, substandard medicines, untreated diseases)

Links between local pharmaceutical value chain development and effectiveness of local healthcare systems (illustrative), 2021. Source: *The European House – Ambrosetti elaboration of Mackintosh, et al. 2017.*

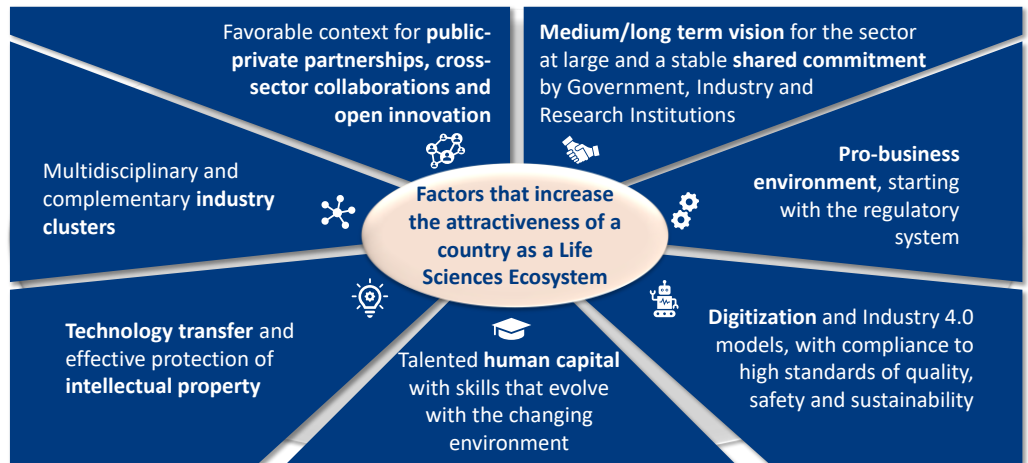
Yet, having acknowledged the strategic importance of this issue, **several questions remain regarding the Sub-Saharan Africa region**: what tools should be prioritized to allow local pharmaceutical industry development in Sub-Saharan Africa's countries? What constraints need to be overcome? What role do national governments play? How can FDI and international partners in the life sciences be attracted? How can cooperation with Italy and its pharmaceutical industry and private sector accelerate this process and increase its feasibility and success? What is the importance of a regional approach?

First of all, the **challenges faced by players in local industry and domestic value chains** must be recognized, and these can be summarized as follows:

- **Disincentivizing market access** that hinders local pharmaceutical production and investment. Even more than elsewhere, in Sub-Saharan African countries there is a strict relationship between government decisions and supply and demand structures. Many governments and health systems in Sub-Saharan Africa still favor imports of finished pharmaceuticals either from multinationals (with which high quality products are associated) or from NGOs and international donors. On the contrary, pharmaceutical inputs (APIs, excipients, packaging, machinery and equipment, etc.) still need to be imported and face higher tariffs and duties.
- **Nonperforming capital market**. Many Sub-Saharan African countries are failing to provide access to affordable financing to local companies in the sector, with high interest rates and capital scarcity coupled with the inability to recognize the specific characteristics of the pharmaceutical sector, which typically faces long development issues and high failure rates in R&D.
- **Lack of technical capabilities and supportive innovation ecosystem**. The pharmaceutical sector is very knowledge-intensive, from early-stage, pre-competitive R&D right up to the highest Technology Readiness Levels and patenting. Adequate skills and human capital are needed. In addition, centers of technical excellence and highly-skilled human capital are required together with state-of-the-art instrumentation and consolidated synergies with highly specialized university and clinical research centers. High skill levels and high quality human capital are also crucial in the other phases of the pharmaceutical value chain, which involve all players and encompass production phases (process industrialization, compliance with efficacy and quality standards, market access activities, etc.). Finally, same level of preparedness is also required for healthcare decision-makers (in charge, for example, of setting standards, purchasing, etc.) and the authorities in charge of pharmacovigilance.



Factors that increase the attractiveness of a country as a Life Sciences Ecosystem, (illustrative). Source: *The European House – Ambrosetti “Meridiano Sanità”, 2021.*



To overcome these constraints, Sub-Saharan Africa **government actions at a national level** are required. Consistent **regulations and policy initiatives** that comply with international standards and recognize local specificities should be enacted. Industrial policy levers must **embrace both the demand and supply side**, by prioritizing business start-up regulations, trade regulations, quality standards and intellectual property laws. Adequate **incentives** should also be provided to the sector (e.g., R&D incentives) together with a **consistent public and public-private framework** that encompasses education and training (e.g., students grants and loans developed together with business, revision of courses to address the needs of the private sector and recognize the most innovative developments in science and technology), the **healthcare sector** (e.g., strengthen supervisory bodies and regulatory authorities that should provide clear guidance for product registration and remodulation of pharmaceutical expenditure) and **business development measures** (e.g., development of industrial parks and trade fairs).

In addition, these efforts should be developed **within a shared regional framework through harmonization of regional regulations and standards and development of multinational strategic outlines.** Setting the basis for a regionally integrated pharmaceutical value-chain with synergic centers of expertise embracing R&D, clinical levels and education, will make it possible to respond effectively to the needs of the continent. It will also allow for maintaining an innovative and competitive ecosystem, capable of ensuring a certain degree of self-sufficiency along the entire value chain in the medium- to long-

term.

The creation of a **supportive capital market** is also key for the development of a competitive pharmaceutical sector in Africa. Among other aspects, **regulatory and legal compliance** must be facilitated for domestic and international investors in the sector. Approval processes for local firms and investors should also be streamlined and accelerated. In addition, **FDI** in the pharmaceutical value chain should be supported. Creation of special economic zones, specifically developed for knowledge-intensive sectors in the field of healthcare and the life sciences could provide an effective tool (cluster approach to manufacturing and services), especially if coordinated at the regional level to avoid overlapping and foster specialization.

Public-private cooperation in R&D activities is also crucial, encompassing international players and public contribution through grants, funding and development of ad hoc fiscal incentives. Development of **regionally-integrated R&D platforms and public research prioritization** could also contribute, especially at the lowest technology readiness levels, which tend to have high levels of risk and long return times.

In addition, for the Sub-Saharan African pharmaceutical industry to reduce import dependence and develop local production, **an increasingly competitive production capacity must be built along the local value chain. Product portfolio expansion, together with formulation skills and R&D capacity must be attained.** In this, links between R&D and clinical institutions and universities on one hand, and industry on the other, are key.



Sub-Saharan Africa countries must reinforce their own research and innovation ecosystems in the field of life sciences, putting public-private cooperation and business initiative at the core of these ecosystems. At the same time, **public guidance is key and public R&D investments are crucial** to sustain this transformation. From the education standpoint, curricula in pharmacy schools and in other academic programs must be reformed to align them with industry requirements.

Finally, **vast room to improve technology-transfer into local production exists through joint ventures or investment by foreign companies**. A first step could involve partnerships in distribution only, which could then be extended into other fields of the value chain, including back into R&D cooperation through technology licensing, capital goods imports, technical assistance and cooperation in education and skills development.

Strategic insights can also be identified for each of the three countries covered by the country focuses presented here. As explained, **South Africa, Ghana and Kenya show a comparative advantage in the pharmaceutical sector**, at least considering their own geographical areas of reference. All three of them can count on a **pharmaceutical sector that includes manufacturing activities, although with different degrees of development**. South Africa can rely on well-established manufacturing base, with a value chain that includes R&D and multinational players. Ghana and Kenya have a lower degree of industrial development but can count on their governments' commitment, both of which have identified the development of a competitive local pharmaceutical industry as a strategic priority.

- **South Africa boasts a leading pharmaceutical industry in Sub-Saharan Africa, with players of excellence in the production of generic drugs and growing competencies in pharmaceutical R&D.** In 2015, industry stakeholders envisioned the South African pharmaceutical industry in 2030 as "a globally competitive pharmaceutical manufacturing industry that is able to supply the majority of its requirements for cost-effective high-quality medicines". For this to be achieved, however, **further progress must be made in the**

development of cutting-edge skills and technical competencies, as well as a strategy for retaining and attracting talent. Furthermore, South Africa can already **act as a regional pioneer, stimulating integration through regional partnerships, sharing of best practices, greater internationalization of supply chains and stimulation of the creation of cutting-edge research and training centers for all of Sub-Saharan Africa**, including through the use of public-private partnerships. At the same time, thanks to the advanced level of development of its financial sector, the country can boost the development of a **capital market** capable of supporting research and investment in the sector.

- **Ghana's pharmaceutical industry is at an intermediate level of development, with a value chain still unbalanced towards distribution.** Some level of manufacturing capacity exists, together with high dependence on foreign inputs, with Asian and European imports dominating supply. The **government has shown a strong commitment to strengthen the domestic pharmaceutical industry**, as outlined in its national health policy. Important measures include: funding for domestic firms to build manufacturing plants, assistance in achieving international standards, tax exemptions and the definition of a list of products and substances that cannot be imported and must be produced locally. At the same time, the government is willing to create partnerships with foreign multinationals on specific dossiers with the goal of empowering local industry and the healthcare ecosystem, and addressing the country's healthcare needs. **The main priority is to upgrade the upstream supply chain, from distribution to some extent of an autonomous manufacturing capability.** This can be pursued through **partnerships with Italian companies** to contribute to improving Ghana's manufacturing standards. At the same time, the government should focus on measures to align education to the needs of business and strengthen the national innovation ecosystem in the field of life sciences.





- **Kenya is currently the leading producer of pharmaceutical products in the Common Market for Eastern and Southern Africa (COMESA) region** with over 30 manufacturing plants and it is the third-largest exporter of pharmaceuticals in Africa. Pharmaceutical manufacturing is also one of the key sectors of focus for the government. However, insufficient drugs are manufactured in Kenya to meet domestic needs. As a result, approximately 70% of locally-used drugs are imported. The sector also relies heavily on imported raw materials for production. Main priorities, acknowledged by the government, include the introduction of **legal, regulatory, institutional and procedural changes towards an overall streamlining and simplification of regulation**. In this sense, **international partnerships can focus, even immediately, on import and distribution, as a first step in initiating the development of a pharmaceutical supply chain with greater manufacturing capabilities**. As of today, the government should not neglect the measures necessary to **create an education and research ecosystem that can support some degree of R&D capacity in the sector in the future**.

In this context, there is **vast room for cooperation with players in the Italian pharmaceutical value chain** and with entities in the Italian innovation ecosystem, including universities, research centers and incubators.

Through partnerships and collaboration, Sub-Saharan African companies will be able to benefit from the ability of Italian companies to **combine high levels of quality, innovation and investment with a solid scientific and industrial tradition, cutting-edge skills and a strong and diversified supply chain** in all phases of the pharmaceutical value chain.

On the other side, **Italian companies can access Sub-Saharan African countries starting from distribution partnerships**, reaching markets characterized by a growing population and increasing consumption and wealth, but also by health issues and national and regional specificities that, if recognized (through those partnerships), could offer vast opportunities for Italian pharmaceutical exports.

Partnerships in distribution, and then, at all levels of the value chain up to R&D can be built in the areas of excellence of the Italian pharmaceutical industry, which include the **biotech sector, vaccines, blood products, orphan drugs and advanced therapies, together with medical devices**.

Important synergies can also be built starting from the increasing relevance of Italy in the clinical phase (which is fundamental for access to therapies and development of the healthcare ecosystem), in which every year in Italy companies invest over €700 million (22% of the EU total, it was 17% in 2015) of which, 42% on biotech drugs and advanced therapies and 32% on rare diseases. In addition, the pharmaceutical sector is first among sectors in Italy for **investments in Open Innovation per employee** and for the share of companies with collaboration agreements with universities and public research centers, reflecting the propensity of Italian pharmaceutical companies to nurture the innovation ecosystem and support its players.

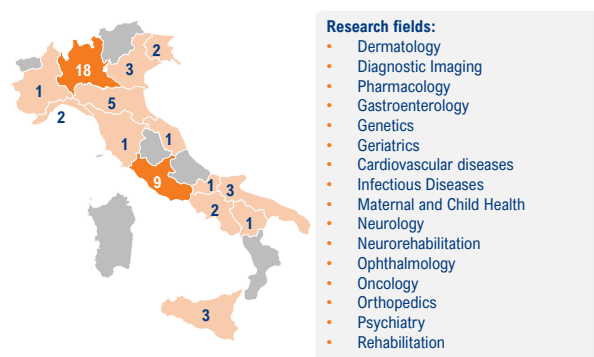
With reference to **biotech drugs**, Italy sees an increase in investments and a significant pipeline of products in development, increasingly in advanced therapies. For **vaccines**, Italy is an international research and production hub, with a solid scientific tradition and a strong vocation for export. Among the specializations, there is also that of **plasma-derived products**, thanks to national companies with a strong international vocation and important companies with foreign capital.

The **Active Pharmaceutical Ingredients** sector represents a high-tech industry in which Italy holds a leading position in the world market, exporting 85% of its production to more than 90 countries. Agreements with Sub-Saharan African local companies through **dossier acquisition** could support local production development and product portfolio expansion.

The Italian pharmaceutical industry is also very **committed to the ecological transition**. In ten years, the sector in Italy has reduced energy consumption by 48% and cut climate-altering gas emissions by 50%, more than the industrial average, and can offer best practices in this regard as well.



Finally, **cooperation between Italy and Sub-Saharan Africa can also extend to the health and clinical sector.** In fact, it is not only the pharmaceutical sector that has a positive impact on the healthcare system of a country. The relationship is two-way: a developed, quality healthcare system can, in fact, permit and support the development of the pharmaceutical sector of a country, nourishing and contributing to clinical research and experimentation, which takes place within and in collaboration with structures of the healthcare system. This circular path can lead local pharmaceutical players to operate in the highest value-added activities of the supply chain such as R&D. In this sense, Italy has a network of facilities of excellence, the **IRCCS (Scientific Institute for Research, Hospitalization and Healthcare) that, alongside clinical activity, promotes research programs with predominantly translational purposes.**



IRCCS network in Italy and fields of research (illustrative), 2021. Source: *The European House – Ambrosetti “Meridiano Sanità”, 2021.*

In conclusion, what we envisage is a **development of the pharmaceutical industry in Sub-Saharan African countries along the entire value chain, gradually becoming increasingly capable of satisfying local health and socio-economic needs** and shaped through a strong regional harmonization that can create synergies between countries and markets and support the development of regional centers of competence.

This development can start, **in the short-medium term, from cooperation with international players in the most downstream stages of the value chain** such as distribution. International players should be selected among those characterized by: high

propensity to export, know-how of excellence and capability to create synergies with the ecosystem of innovation and with the local healthcare systems. At the same time, Sub-Saharan African governments will have to create a supportive environment, implementing the required measures in the fields of business development, capital market and healthcare. In addition, they should incentivize the development of local innovation ecosystems and support skills development in life sciences to respond to the needs of both local players and foreign companies investing in these countries. **In the medium-long term, FDI and partnerships could scale up, involving all areas of the value chain.**

An important link between Italian and Sub-Saharan African companies—starting from those countries showing higher levels of development of their local value chains or more opportunities for collaboration such as South Africa, Ghana and Kenya—can be played by organizations such as **ITA (Italian Trade and Investment Agency). It already supports the internationalization activities of Italian players in the sector through the organization of several intertwined initiatives** including: studies and analysis in target countries, follow-up actions, and B2B meetings in person or through digital platforms. In addition, ICE organizes the Technological Days, bringing Italian players to visit foreign production sites and organizing meetings with local counterparts. ICE also supports the collective participation of Italian companies in prestigious trade fairs.