



Cross-border markets for innovation: Biopharmaceutical regulations in Africa

- On November 29th 2023, the WAITRO Secretariat hosted a webinar introducing an overview of the African biopharmaceutical market landscape and market access policies. This report summarizes the goals, presentations and lessons learned from the webinar.

Welcome and Introduction
Dr. Paul E. Burrows
Secretary General, WAITRO
Vice President, JITRI



WAITRO’s Mission focuses on the UN Sustainable Development Goals, or SDGs, that were launched in 2015 and targeted at the year 2030. In fact, we just hit the halfway point to the SDGs. The recent Global Sustainable Development Report from the UN, which you can find online, highlights the uneven progress in achieving the SDGs and, particularly, the need for research, technology and innovation coupled to local needs, or what they call “socially robust science” to get the SDGs back on track.

Sustainable economic development requires innovation, but innovation needs a market in which to take root and grow. Multiple surveys of failed technology startups have shown that, in the vast majority of cases, failure was not a fault of the technology, but rather of an inability to create or connect to a market.

WAITRO is a global Association of Organizations... each WAITRO member is a research technology organization or industry player with strong connections to its local markets. And each local market is different, with different needs, different opportunities and different challenges.

WAITRO’s global reach gives it the potential to facilitate entrepreneurship across borders and to connect innovation with the unique market conditions that exist in places as diverse as Europe, Asia, the Americas, and (the focus of today’s webinar) Africa. In doing so, we can enable local solutions to achieve global impact, and help advance the SDGs around the world.

How to access global markets for both WAITRO’s Research Technology Organizations and industry focused Associate Members is the focus of this new workshop series; how to help both our member organizations, and the individuals that are the source of innovation at those organizations, optimize their entrepreneurial potential.

I look forward to learning from the results. Please give us feedback both in the comments here and offline via our website and social media channels. On behalf of the WAITRO Secretariat, welcome to this new workshop. Thank you for giving us your time, and I hope you both contribute to the discussion and gain value from it.

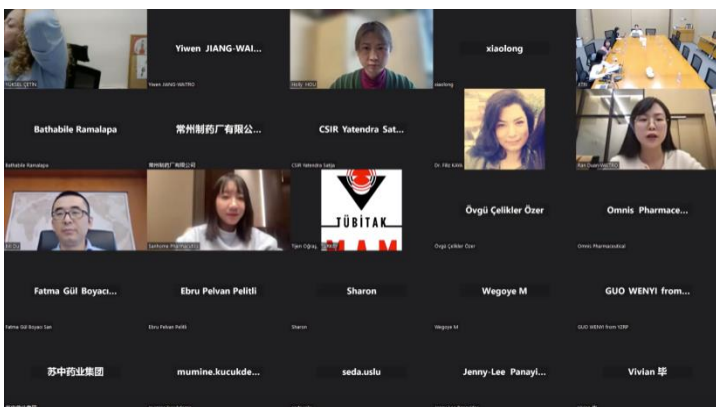
Executive Summary

Background:

Africa, a continent with 54 countries, constitutes a diverse pharmaceutical market. While Africa only currently holds approximately 3% of the international pharmaceutical market share, in total around USD 40 billion, its market is rapidly growing due to rates of birth, urbanization, and industrialization that are higher than the global average¹. The impact of the recent pandemic has strengthened international calls to localize more production in Africa, making it a popular destination for establishing pharmaceutical research and manufacturing industries. Africa is poised to become a significant growth market in the future of the pharmaceutical industry.

Due to factors such as decades of import reliance on pharmaceutical products coupled with segmented market regulatory policies, the African market poses excellent opportunities and challenges for foreign and local pharmaceutical companies regarding information, technology, business capabilities, policy analysis, and resource planning.

The webinar advocated for Africa's biomedicine capabilities amid a global shift in medical research focus towards African countries. It challenges stereotypes by highlighting South Africa's modern pharmaceutical R&D and regulatory systems. While progress is evident, systemic and policy gaps persist across the continent, emphasizing diverse market needs. This diversity suggests a context-tailored partnership strategy. The webinar urged a rethink, promoting localized, culturally relevant research and market access collaborations with African institutions and policy experts to strengthen the continent's pharmaceutical industry.



¹ IQVIA. Africa's next chapter: a continent of opportunity. September 22,2023. Available at: <https://www.iqvia.com/blogs/2023/09/africas-next-chapter-a-continent-of-opportunity>.

Time and Date:

Wednesday, November 29 | 08.30h – 10.30h UTC+1 (CET)

Wednesday, November 29 | 09.30h – 11.30h SAST

Wednesday, November 29 | 15.30h – 17.30h GMT+8

Goals:

The **WAITRO Secretariat China** hosted the webinar to develop an overview of the African bio-pharmaceutical market landscape and relevant market access policies. The webinar featured five experts from the pharmaceutical industry in Africa and China, discussing the potential for pharmaceutical market development in Africa, the policy and regulatory environment, unique aspects of the African market, payers, and procurement mechanisms, aiming to provide a comprehensive view of the opportunities and challenges for pharmaceutical businesses in Africa.

Key Insights

Over 40 experts in regulations and manufacturing technology, business representatives, and researchers joined the webinar to focus on Africa's Bio-medicine Market. We were thrilled to unfold a picture of the African pharmaceutical regulatory framework and manufacturing capacity for the 60% of our audience who had no earlier opportunity to access this information!

Dr. Bathabile Ramalapa depicted the regulatory framework on medical products in South Africa, Consumer Protection, Biopharmaceutical market policies and Access, pricing regulatory framework on the medicines from both public and private sectors, and marketing code authority.



Dr. Jenny-Lee Panayides introduced existing local capacity in the manufacturing of essential medicines in Africa, as well as several scientific initiatives of South Africa, and Mr. Adane Demeke Moloro presented the healthcare landscape and the demand for drugs in Ethiopia, from a government perspective.



Mr. Bill Du, Ms. Menghan LIU, and Ms. Wenjun LIU from the pharmaceutical commercial sector shared their readings as seasoned pharmaceutical business professionals on the challenges and opportunities of entering a new international market. The commercial arm of biomedicine called for cross-border collaboration with local African experts and institutions.

Company Overview

Jiangsu Aidea Pharmaceutical Co., Ltd. ("Aidea Pharma", 688488.SH) was established in 2009 and listed on the Shanghai Stock Exchange STAR Market in 2020. As a high-tech pharmaceutical company, Aidea Pharma focuses on the development of anti-HIV/AIDS product portfolio while leveraging its competitive advantages in the field of

Cooperation Demand

- ▶ Welcome African botanical medicines to enter China, and we are looking forward to develop cooperation in the field of gynecology, pediatrics, nephrology, and other good varieties.
- ▶ Regarding Huangkui capsules, if there was a clinical demand in Africa ,we are also looking forward to cooperation, and we hope to welcome more friends and partners to participate in the internationalization of Huangkui Capsule and benefit more patients suffered from kidney disease!

Audience:

The audience included representatives from five WAITRO regions: Sub-Saharan Africa, Asia and the Pacific, North America, Europe and even one from Latin America (where it was very early in the morning). They were from diversified backgrounds such as medical researchers, pharmaceutical regulatory professionals, business development professionals, and drug developers.

Sanhome at a Glance



Sanhome was founded in 1996 by Yong Wang.
One of the earliest companies in China to obtain GMP certification.
Primary focus on oncology and anti-infection fields.
More than 1,500 employees in China
Products marketed throughout China with more than 1 billion RMB in revenue per year

At Sanhome, we abide by three core values that have been part of our foundation for many years.



Mission

Let more people enjoy happiness of healthy.



Vision

Become the most trusted partner for doctors and patients.



Goal

Become a world-class pharmaceutical company.

Collaborative opportunities identified

On the motivation to join the webinar, most of them were seeking for medical and pharmaceutical research partner in Africa. In future, audiences were looking for partnership in a research center affiliated to university, to identify manufacturing partner, and a sophisticated, detailed introduction on African regulatory framework.

The webinar provides a timely advocacy for Africa's capability in biomedicine. As global attention and resources in medical research, development, and production increasingly turn towards African countries, there is a shift towards building a resilient and self-reliant pharmaceutical industry. For audiences unfamiliar with Africa, their outdated stereotypes of the African market are challenged, with countries like South Africa showcasing modern pharmaceutical R&D and regulatory systems. However, systemic and policy gaps persist on the continent, highlighting diverse market needs and expandability potential across African countries. Consequently, a one-size-fits-all partnership strategy is not applicable. The webinar encourages audiences to

reconsider establishing localized, culturally appropriate research, and market access partnerships with African institutions and policy experts.

Conclusions

- Webinars such as this are a useful approach to bring together global efforts for achieving SDG3. WAITRO has always aimed to foster innovation and drive sustainable development by empowering member organizations and facilitating collaboration across borders and boundaries. The webinar is a good approach to realize the global efforts to advance SDG3.
- The WAITRO global innovation network bridges technical and partnership interests of its members. The webinar began with the technology demands of companies of JITRI ecosystem; they are doing research and commercialization on the pharmaceutical products and would like to find clinical research partners. Meanwhile, research institutes in Africa are also seeking joint research partners. The webinar provided a good opportunity for both parties to match research partners and should be expanded globally.
- Call to action: what are the next steps for stakeholder engagement in light of the shared insights? The webinar could be the first of many in the future; it brings together the local innovation resources to encourage more cooperation across borders. Stakeholders can be introduced to more value and opportunities via the event and follow-up communication.
- Learnings: The African biomedicine industry is highly divergent in needs, research capability, regulatory system maturity, and business infrastructures. Seeking partnership in this continent must have context-tailored strategies that acknowledge local capacity, expertise, and industrial eco-system, and with a mutually beneficial vision.

About the Webinar Partners:

CSIR

The Council for Scientific and Industrial Research (CSIR) is a leading scientific and technology research organization that research, develops, localizes and diffuses technologies to accelerate socioeconomic prosperity in South Africa. The organization's work contributes to industrial development and supports a capable state.

The CSIR was established through an Act of Parliament in 1945 and the organization's executive authority is the Minister of Higher

Education, Science and Innovation. The organization plays a key role in supporting public and private sectors through directed research that is aligned with the country's priorities, the organization's mandate and its science, engineering and technology competences.

Impact is at the core of our business and the following objectives are crafted to ensure that we achieve our mission:

- Conduct research, development and innovation of transformative technologies and accelerate their diffusion;
- Improve the competitiveness of high-impact industries to support South Africa's re-industrialisation by collaboratively developing, localising and implementing technology;
- Drive socioeconomic transformation through RD&I that supports the development of a capable state;
- Build and transform human capital and infrastructure; and
- Diversify income, and maintain financial sustainability and good governance.

Our core values are EPIC (Excellence, celebrates People, personifies Integrity) and they are the driving force behind our ability to conduct cutting-edge research and technological innovation to improve the quality of life of South Africans. The CSIR welcomes Collaboration. For more information: <https://www.csir.co.za/>

- **Nanjing Sanhome Pharmaceutical Co. Ltd**

Sanhome Pharmaceutical is a national high-tech enterprise integrating new drug R&D, production and business development. It maintains three main sectors: academics, R&D, and supply chain, supported by functional departments and service units. Specializing in producing and selling chemical medicines and modern finished drugs derived from traditional Chinese medicines. It provides 30+ drugs in 10+ formulations, for domestic and international markets. The company

currently focuses on bio-medicines, chemical pharmaceuticals and new treatments, and is expanding its market into bio-pharmaceuticals and biologic therapies.

- **Suzhong pharmaceutical group**

Suzhong Pharmaceutical is a modern health industry group integrating pharmaceutical manufacturing, pharmaceutical marketing, and the health industry. The company possesses more than 10 manufacturing facilities covering various types of formulations, producing 180 medicines, including Chinese traditional medicines, chemical medicines, marine-derived pharmaceuticals, and biological medicines. Suzhong receives recognition from fellow domestic and international experts. Suzhong Pharmaceutical Group is now considered one of China's few comprehensive and large-scale drug manufacturers, setting an example.

- **Aidea Pharma**

Aidea Pharma is a hi-tech pharmaceutical firm dedicated to R&D, production, and medicine sales. The company specializes in human protein-based therapeutics and anti-HIV agents, focuses on the major diseases, and has built R&D pipelines in anti-HIV, anti-inflammation and cerebral stroke. The company actively explores, develops, and sells innovative medicines, taking the unmet clinical needs as orientation. Aidea invests in strengthening its commercial capabilities to establish operations in China, with ambitions to become a global player within these domains.

Keynote speakers:

- **Mr. Adane Demeke Moloro**, Public Health Professional Specialist at Ministry of Health, Ethiopia. He holds a bachelor degree in occupational health and security, and an International Master of Public Health from Vanke School of Public Health, Tsinghua University China. Before joining Ethiopian Ministry of Health, Mr. Moloro has served 12 years for the Ethiopia Food and Drug Authority as environmental health and safety regulatory expert.



- **Dr. Bathabile Ramalapa** Senior Researcher at CSIR. She holds a PhD in Chemical Sciences from the University of Liege in Belgium and another in Pharmaceutical Sciences from the University of Angers in France. She is a biotechnologist by training with over 10 years international experience working with biopharmaceuticals. She has research expertise in the development of pharmaceutical and nutraceutical formulations for optimal human health and a track record of publications in high impact factor journals. Her current role at the Council for Scientific and Industrial Research involves management of research projects and facilitating collaborations with stakeholders from government, academia and private industry in the biotechnology space. Her main research focuses on the development of advanced drug delivery systems for diseases with a high burden in Africa. Bathabile is passionate about providing innovative biotechnology solutions to Africa's problems, which can be exported globally.



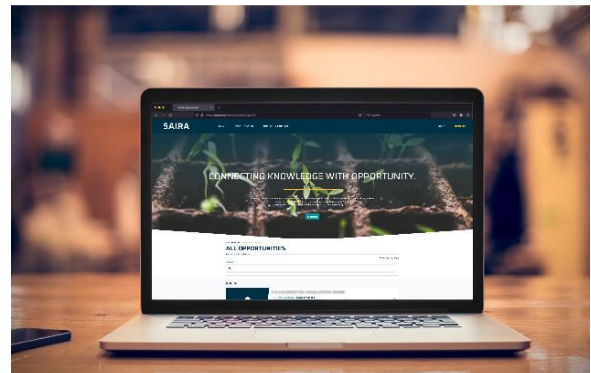
- **Dr. Jenny-Lee Panayides** Research Group Leader & Principal Researcher at CSIR. She holds a PhD in the fields of synthetic organic chemistry and microbiology from the University of the Witwatersrand. She joined the CSIR in 2012 and has acted as principal investigator for projects investigating synthetic libraries for activity against various strains of *Plasmodium falciparum* in order to identify novel chemical entities that are active against multiple strains of drug-resistant malaria; and investigating the preparation of microsphere-supported catalysts and their application to both batch and flow syntheses for use in local active pharmaceutical ingredient manufacturing.



She is currently part of a local consortium that is focused on the structure-aided discovery of novel treatments for Alzheimer’s disease. She has assisted on international projects focused on using intra-erythrocytic stage gametocyte assays for the screening of a library of 250 000 compounds for inhibitory activity against *Plasmodium falciparum*, the development of a single-dose cure for the treatment of malaria and investigating inhibitors as targeted therapeutic agents for breast cancer.

WAITRO Products to Help

Looking for partners for a research project relevant to *any* of the SDGs? Try registering for WAITRO’s SAIRA platform and then posting it as a challenge! SAIRA emerged from a project supported by the Federal Ministry of Education and Research (BMBF), initially aiming to enhance global connections among researchers and promote international collaboration.



The platform’s current success underscores its effectiveness in facilitating meaningful net- working within the research community with well over 1300 users in 124 countries around the globe and over 50 successful matches to make project teams. In 2024, WAITRO aspires to augment its value by extending benefits to additional stakeholders, such as start-ups, companies, and impact investors.



WAITRO Members are welcome to submit information about their contributions to the UN Sustainable Development Goals (SDGs), including SDG3 Good Health and Well-Being for promotion on the website and WAITRO’s social media channels. Build your brand with WAITRO and reach out to potential partners in research or development and customers in business. Anyone interested (whether an employee of a member or not) is welcome to sign up for the WAITRO Newsletter on the landing page of the WAITRO website.

Register for SAIRA: www.saira.eco

Stay updated with the WAITRO Newsletter: www.waitro.org