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or speed post or in person,
to the adjudicating officer
regarding contravention of
the provisions of the Act.

The Adjudicating Officer,
an officer authorised under
Section 43A of the Act, will
issue show cause notice to
the person against whom
such complaint has been
filed, and can proceed with
further notice of appearance
of the person or through a
representative if the officer
is of the opinion that an in-
quiry should be held.

In taking any evidence
under these regulations, the
adjudicating officer shall
not be bound to observe the
provisions of the Bharatiya
Sakshya Adhiniyam, 2023.

"If, upon consideration of
the evidence produced be-
fore the adjudicating offi-
cer, the adjudicating officer
is satisfied that the person
has committed the contra-
vention, he may by order in
writing, impose such pen-

alty under the Act, as he
considers reasonable," said
the new regulation.

Every such order shall
specify the provision of the
Act in respect of which con-
travention has been com-
mitted and shall contain
the reasons for imposing
the penalty.

The adjudicating officer
shall complete the proceed-
ings within six months
from the issuance of the no-
tice to the opposite party,
it added.

Any person aggrieved
by an order of the adjudi-
cating officer under these
regulations, may prefer an
appeal to the appellate au-
thority in Form-IV, which
has been notified along
with the regulation.

The appeal shall be filed
with the appellate author-
ity within a period of forty-
five days from the date of
receipt of the order.

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Africa pharma stands at critical crossroad in evolution

Dr. Sanjay Agrawal

AFRICA stands at a critical crossroads in its healthcare and pharmaceutical evolution. With a population exceeding 1.4 billion and projected to reach 2.5 billion by 2050, the continent presents both a profound challenge and an extraordinary opportunity in the global health ecosystem.

For decades, the pharmaceutical landscape in Africa has been characterized by heavy reliance on imported drugs, with over 70-90 per cent of medicines sourced from international markets such as India, China, and Europe. This dependency has long exposed the continent to external shocks—supply chain disruptions, fluctuating pricing, and delays in access to life-saving drugs.

The Covid-19 pandemic starkly exposed the vulnerabilities of this dependency. While wealthier nations secured large vaccine stockpiles through advanced purchase agreements, African countries were left scrambling for access. This disparity catalyzed a continental



reckoning: the urgent need for self-reliance in pharmaceutical production, distribution, and regulation. As a result, governments, pan-African institutions, private stakeholders, and global partners are now aligning to reshape the continent's pharmaceutical future from the ground up.

The pharmaceutical industry in Africa, once a fragmented and underdeveloped sector, is undergoing a significant transformation. In recent years, several African nations have begun investing in local manufactur-

ing, research, and innovation. Initiatives such as the African Medicines Agency (AMA), the African Vaccine Manufacturing Initiative (AVMI), and the African Continental Free Trade Area (AfCFTA) are building foundational frameworks to support regulatory harmonization, regional cooperation, and investment in health infrastructure.

Moreover, there's a growing awareness that improving the pharmaceutical sector is not only a health imperative but also an economic one. Lo-

cal production of medicines and vaccines can contribute to industrialization, job creation, skill development, and the reduction of import bills—key priorities for many African governments striving for economic independence and sustainable growth.

Simultaneously, the burden of disease in Africa is shifting. While communicable diseases like malaria, HIV/AIDS, and tuberculosis still present major public health threats, non-communicable diseases (NCDs) such as diabetes, cardiovascular conditions, and cancer are rising rapidly due to urban-

ditional medicine as part of a holistic health approach, particularly in rural and underserved areas.

Against this backdrop, the African pharmaceutical market is being recognized not just as a zone of need, but as a frontier of growth, innovation, and collaboration. Analysts forecast that the value of the pharmaceutical industry in Africa could reach between \$60-70 billion by 2030, up from just over \$20 billion in 2013. This remarkable potential hinges on solving key challenges such as regulatory fragmentation, inadequate financing, infrastructure gaps, and the scourge of counterfeit drugs.

This article delves into the multiple dimensions of Africa's pharmaceutical journey. From market dynamics and regulatory reforms to the integration of digital health and the rise of local manufacturing hubs, we will examine how Africa is reimagining its pharmaceutical identity—transforming from a passive consumer of global health goods to an active producer and innovator. As the continent rises to meet its health challenges, the pharmaceutical sector may well

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ization, lifestyle changes, and aging populations. This epidemiological shift demands a more diversified pharmaceutical ecosystem capable of responding to both traditional and emerging health threats.

Importantly, Africa is not starting from scratch. The continent is home to some pioneering pharmaceutical companies—such as Aspen Pharmacare in South Africa and Cipla Quality Chemical Industries in Uganda—that are already demonstrating the feasibility of local drug manufacturing. In parallel, there is renewed interest in leveraging indigenous knowledge systems and tra-

ditional medicine as part of a holistic health approach, particularly in rural and underserved areas.

Current landscape

Africa's pharmaceutical market is experiencing significant growth, driven by factors such as population expansion, urbanization, and increased healthcare awareness. Key insights include:

- Market size and growth:** The pharmaceutical market in Africa is projected to experience substantial growth, with an expected compound annual growth rate (CAGR) of 6-8 per cent between 2024 and 2029.

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AMA aims to improve quality and availability of medicines

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This growth is fueled by a rising population, increasing urbanization, growing incidence of chronic diseases, and greater healthcare expenditure.

■ **Import dependency:** Despite growth, Africa remains heavily dependent on imports, with up to 90% of pharmaceutical products being imported. This reliance underscores the need for bolstering local manufacturing capabilities.

■ **Local manufacturing:** Local vaccine production currently meets less than one per cent of the continent's demand in value, highlighting the need for increased local manufacturing capabilities.

Challenges sector faces

Several obstacles hinder the development of a robust pharmaceutical industry in Africa:

■ **Infrastructure deficits:** Many regions lack the necessary infrastructure for pharmaceutical manufacturing, including reliable electricity, water supply, and transportation networks.

■ **Regulatory hurdles:** The absence of harmonized regulatory frameworks across countries leads to inefficiencies and delays in drug approval processes.

■ **Counterfeit medicines:** The prevalence of counterfeit and substandard medicines poses significant health risks and undermines public trust in healthcare systems.

■ **Skilled workforce shortage:** There is a deficit of trained professionals in

pharmaceutical sciences, affecting research, development, and manufacturing processes.

Initiatives and innovations

Despite these challenges, numerous initiatives are paving

the way for a more self-reliant pharmaceutical sector:

■ **African Medicines Agency (AMA):** Established to harmonize medical regulations across the continent, the AMA aims to improve the quality and availabil-

ity of medicines. It supports the growth of local pharmaceutical production and plays a critical role in catalyzing trade in support of the Africa Continental Free Trade Area (AfCFTA).

■ **Local manufacturing efforts:** Companies like Aspen Pharmacare in South Africa are leading efforts in local drug manufacturing, including antiretrovirals and antimalarials.

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AMA must be empowered to establish uniform standards

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- **Vaccine production:** African Biologics in South Africa is pioneering mRNA vaccine development, aiming to address diseases prevalent in Africa.
- **Public-private partnerships:** Collaborations between governments and private entities are fostering investment in pharmaceutical infrastructure and research.

Role of traditional medicine

Traditional medicine remains integral to healthcare in many African communities;

- **Integration into modern healthcare:** Efforts are underway to scientifically validate and integrate traditional remedies into mainstream healthcare, ensuring safety and efficacy.
- **Research and development:** Institutions are exploring the potential of indigenous plants and knowledge systems in developing new treatments.

Future outlook

The trajectory of Africa's pharmaceutical sector is promising:



- **Economic growth:** Continued economic development is expected to increase healthcare spending and demand for pharmaceuticals.
- **Technological advancements:** Adoption of digital technologies, such as telemedicine and e-pharmacies, is enhancing access to healthcare services.
- **Regional collaboration:** Initiatives like the African Continental Free Trade Area (AfCFTA) are facilitating cross-border trade and investment in pharmaceuticals.
- **Global partnerships:** En-



gagements with international organizations and companies are bringing in expertise, funding, and technology transfer.

Strategic roadmap for resilient African pharma industry

For Africa to truly transition from pharmaceutical dependency to self-sufficiency, it must embrace a bold and coordinated strategy that aligns national strengths with continental goals. The future of African pharma doesn't lie in isolated efforts but in regionally integrated, innovation-driven ecosystems that can compete on a global scale.

a) Build regional pharma manufacturing hubs

Rather than duplicating full-scale infrastructure in every country, Africa can benefit by developing specialized regional hubs for pharmaceutical production. For instance, one region might focus on producing active pharmaceutical ingredients (APIs), while another specializes in drug formulation and packaging. This model would lower production costs, reduce duplication, and build economies of scale.

b) Activate potential of AfCFTA

The African Continental

Free Trade Area (AfCFTA) is a game-changer. By eliminating intra-African tariffs and harmonizing cross-border policies, AfCFTA can enable locally manufactured medicines to flow freely across countries, fostering competitive pricing, faster delivery, and regional drug availability. A unified continental market would also make Africa more attractive for pharmaceutical investment and clinical trials.

c) Strengthen regulatory harmonization through AMA

The African Medicines Agency (AMA) must be empowered to establish uniform pharmaceutical regulatory standards, accelerating drug approvals and ensuring product safety across the continent. This harmonization is essential for scaling up manufacturing, ensuring global compliance, and minimizing counterfeit risks.

d) Scale public-private-global partnerships

Africa's pharmaceutical future requires deeper collaboration between governments, local pharma companies, academic institutions, and global industry leaders. By fostering joint ventures, incentivizing local R&D, and investing in workforce development, Africa can bridge its technical gaps. Technology transfer, particularly in vaccine manufacturing and advanced therapeutics, should be at the heart of these collaborations.

e) Bolster API production capacity

Currently, Africa imports the vast majority of APIs used in medicine production. By investing in local API synthesis facilities, particularly in countries with strong chemical engineering

capabilities like Egypt, South Africa, and Nigeria, the continent can drastically reduce its reliance on imports and im-

Conclusion

Africa's journey towards pharmaceutical self-sufficiency is marked by both challenges and opportunities. By addressing infrastructural deficits, enhancing regulatory frameworks, and fostering innovation, the continent can build a resilient pharmaceutical industry that meets the health needs of its population. Collaboration among governments, private sector, and international partners will be crucial in realizing this vision.

(The author is Scientific Advisor, ALKOMEX GBN PHARMA GROUP U.S.A.)

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