

African Region

REGIONAL COMMITTEE FOR AFRICA**ORIGINAL: ENGLISH**Seventy-fourth sessionBrazzaville, Republic of Congo, 26–30 August 2024Provisional agenda item 10**FRAMEWORK FOR STRENGTHENING LOCAL PRODUCTION OF MEDICINES,
VACCINES, AND OTHER HEALTH TECHNOLOGIES IN THE WHO AFRICAN
REGION 2025–2035****Report of the Secretariat****EXECUTIVE SUMMARY**

1. Strengthening local production is a strategy that should be collaboratively pursued to improve access to quality, safe, efficacious, and affordable medicines, vaccines, and other health technologies. This will significantly contribute to improving supply chains, strengthening health security, and facilitating the attainment of universal health coverage (UHC) and the health-related Sustainable Development Goals (SDGs) and their respective targets.
2. Member States of the WHO African Region import between 70% and 100% of finished pharmaceutical products (FPPs), 99% of vaccines, and between 90% and 100% of medical devices and active pharmaceutical ingredients (APIs), with little or no capacity for manufacturing of pharmaceutical quality excipients, vaccines, medical devices, and other health technologies.
3. Out of 45 regulatory systems benchmarked between April 2019 and November 2022, forty-one were found to be at WHO Maturity Levels 1 and 2, that is, operating without a formal approach or evolving to partially implement the nine Global Benchmarking Tool (GBT) regulatory functions, while only four¹ were at Maturity Level 3, which is the minimum required for good regulatory oversight. The low maturity levels negatively impact the Region's capacity to provide appropriate regulatory oversight to ensure quality, safe and efficacious products, and limit the circulation of substandard and falsified products.
4. Market fragmentation and lack of reliable market intelligence information required for sustainable local production, development, and planning constitute challenges, some of which could be alleviated by pooled procurement mechanisms.
5. Mitigating these challenges requires the implementation of comprehensive and cohesive policies within countries, as well as improved collaboration and cooperation among Member States.
6. African leaders have demonstrated their commitment to boosting local production, strengthening regulatory systems and implementing pooled procurement mechanisms. However, successful

¹ Ghana, March 2019; Nigeria, February 2022; United Republic of Tanzania, May 2018 (medicines and non-vaccine manufacturing); and South Africa, September 2022 (vaccine manufacturing).

implementation of the related frameworks remains a challenge due to inadequate resources, capacity and lack of coordination within and among Member States.

7. World Health Assembly resolutions WHA74.6 and WHA67.20 mandated the WHO Secretariat to continue supporting Member States, at their request, in promoting quality and sustainable production of medicines and other health technologies, and to strengthen regulatory systems.

8. This framework presents a unitary vision, goals, objectives, regional targets and milestones, aimed at facilitating monitoring and evaluation of progress towards addressing the identified gaps in the regional manufacturing ecosystem.

9. To achieve the stated vision, goal and objectives, guiding principles such as ownership and governance, human rights and equitable access, a holistic approach and multisectoral collaboration, have been proposed to guide the planning and implementation of priority interventions.

10. The subject priority interventions include the development and implementation of comprehensive and cohesive national and regional policies and legal frameworks as well as related governance structures, strengthening of regulatory systems, investment in research and development, enhancing and facilitating technology transfer, increasing the availability of a skilled health workforce, and access to finance.

11. This framework aims to guide Member States in the planning and implementation of strategic actions to establish and scale up local production to increase access to medicines, vaccines, and other health technologies.

12. The Regional Committee is invited to examine and adopt the actions proposed.

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ABBREVIATIONS

AfCFTA	African Continental Free Trade Area
AMA	African Medicines Agency
API	active pharmaceutical ingredient
AUDA-NEPAD	African Union Development Agency
cGMP	current good manufacturing practice
EAC	East African Community
ECOWAS	Economic Community of West African States
FTE	full-time equivalents
ML 3	Maturity Level 3
mRNA vaccines	messenger ribonucleic acid vaccines
NRA	national regulatory authority
PMPA	Pharmaceutical Manufacturing Plan for Africa
SADC	Southern African Development Community
SDGs	Sustainable Development Goals
UHC	universal health coverage
WAHO	West African Health Organization
WHA	World Health Assembly
WHO GBT	WHO Global Benchmarking Tool

INTRODUCTION

1. The COVID-19 pandemic demonstrated the acute need for the Region to review its dependence on global medical product supply chains. Health emergencies, disease outbreaks and conflict situations have underscored the need for and accelerated the prioritization by African leaders of the establishment and scale-up of local production at both country and regional levels. This will mitigate the risk of supply chain disruptions and bring production closer to the end-users, and also facilitate the achievement of health security, attainment of UHC and the health-related SDGs and their respective targets.
2. The Seventy-fourth World Health Assembly in 2021 adopted resolution WHA74.6 on strengthening local production of medicines and other health technologies to improve access.² It urges Member States, among other actions, to strengthen their leadership, commitment and support in promoting the establishment and strengthening of quality and sustainable local production of medicines and other health technologies based on good manufacturing practices.
3. This framework supports the implementation of WHA74.6 and aims to guide African Member States in planning and implementing priority interventions to establish and scale up local production that will increase access to medicines, vaccines, and other health technologies in the Region. The framework aligns with other existing regional and continental initiatives.
4. Member States and partners may use this regional framework as a guide to develop and implement strategic interventions for strengthening local production at country and regional levels with contextualized targets and/or milestones that are aligned to this framework to facilitate data collection and reporting at regional level.

CURRENT SITUATION

5. In the African Region, between 70% and 100% of medicines and other medical products, 99% of vaccines, and between 90% to 100% of medical devices³ are imported, with very limited or no manufacturing capacity for active pharmaceutical ingredients (APIs), drug substances for vaccines, and medical devices. There are 649 pharmaceutical manufacturing plants in Africa, with 29 countries having varying drug manufacturing capabilities.⁴ In comparison, China and India have roughly the same population as the African Region and have 5000 and 10 500 drug manufacturers, respectively.⁵
6. There is strong leadership and political commitment for the establishment and scale-up of local production as evidenced by several regional and continental frameworks and initiatives including the following:
 - (a) Pharmaceutical Manufacturing Plan for Africa (PMPA): Business Plan (2012),⁶ by the African Union Commission and United Nations Industrial Development Organization,

² World Health Assembly resolution WHA74.6 (2021) on Strengthening local production of medicines and other health technologies to improve access.

³ The Institute for Economic Justice. The localisation of medical manufacturing in Africa; 2022 (https://www.iej.org.za/wp-content/uploads/2022/11/IEJ-LoMMiA-report_Nov2022.pdf; accessed 3 February 2024)

⁴ The Institute for Economic Justice. The localisation of medical manufacturing in Africa; 2022 (https://www.iej.org.za/wp-content/uploads/2022/11/IEJ-LoMMiA-report_Nov2022.pdf; accessed 3 February 2024)

⁵ McKinsey & Company. Should sub-Saharan Africa make its own drugs? 2019 (<https://www.mckinsey.com/industries/public-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs>, accessed 4 February 2024)

⁶ African Union Development Agency. Pharmaceutical Manufacturing Plan for Africa : Business Plan; 2012 (<https://www.nepad.org/publication/pharmaceutical-manufacturing-plan-africa>, accessed 7 February 2024)

- (b) Economic Community of West African States (ECOWAS) Regional Pharmaceutical Plan 2014,⁷
- (c) 2nd East African Community (EAC) Regional Pharmaceutical Manufacturing Plan of Action 2017–2027,⁸
- (d) Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action,⁹ whose vision is to manufacture 60% of vaccines needed on the continent by 2040,
- (e) African Medicines Regulatory Harmonization (AMRH) initiative, with WHO and AUDA-NEPAD serving as the joint secretariat,
- (f) Regional regulatory harmonization and work-sharing initiatives, and
- (g) The African Medicines Agency (AMA) Treaty.

7. While various regional frameworks have been developed to boost local production, implementation remains a challenge due to inadequate resourcing, other competing priorities, limited capacity and lack of appropriate coordination within and among Member States.

8. Between April and June 2023, a WHO African Region local production questionnaire survey was piloted among 14 large, medium, and smaller pharmaceutical and vaccine manufacturing and non-manufacturing countries,¹⁰ to which seven countries¹¹ responded. It found that only 50% or less of local manufacturers were certified good manufacturing practice (GMP)-compliant by their national regulatory authorities (NRAs), emphasizing the need to facilitate compliance of local industry with current GMP (cGMP). It also found that complex formulations such as newer noncommunicable disease treatment formulations, chemotherapeutic and inhalation products that are in the WHO Essential Medicines List, were neither manufactured nor part of the product ranges. Five countries stated that their NRAs had regulatory oversight on medical devices, including in vitro diagnostics (IVDs).

9. Forty-five Member States in the African Region have had their NRAs benchmarked using the WHO Global Benchmarking Tool (WHO GBT). Only Ghana, Nigeria, South Africa and United Republic of Tanzania have achieved WHO Maturity Level 3 (WHO ML 3) status confirming the existence of a stable, well-functioning and integrated regulatory system. The remaining 41 countries are at Maturity Levels 1 or 2.

10. WHO continues to support Member States to establish and scale up local production. Work is carried out in collaboration with partners including the Africa Centres for Disease Control and Prevention (Africa CDC), the African Union Development Agency (AUDA-NEPAD), the European Union (EU) and others. Member States are supported through capacity building, ecosystem assessments and development of road maps, regulatory system strengthening, and support for policy development.

⁷ West African Health Organization. The Economic Community of West African States (ECOWAS) Regional Pharmaceutical Plan; 2014 (https://www.wahooas.org/web-ooas/sites/default/files/publications/1086/Resolution_ECOWAS_Regional_Pharmaceutical_Plan_Engl.pdf; accessed 4 February 2024)

⁸ East African Community. 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017-2027 (<http://repository.eac.int/handle/11671/24343>, accessed 4 February 2024)

⁹ AU, Africa Centres for Disease Control. Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action; 2022

¹⁰ Botswana, Eswatini, Ethiopia, Ghana, Kenya, Liberia, Madagascar, Mauritius, Nigeria, Rwanda, Senegal, South Africa, Uganda and United Republic of Tanzania

¹¹ Botswana, Ghana, Liberia, Madagascar, Nigeria, Uganda, and United Republic of Tanzania

11. In addition, access to technology transfer is facilitated through the mRNA vaccine technology transfer hub supported by WHO and its partners and located within Afrigen Biologics and Vaccines, Cape Town, South Africa,¹² and the WHO Biomanufacturing Workforce Training Initiative.

ISSUES AND CHALLENGES

12. **Inadequate policy coherence and legal frameworks:** Existing policies and legal frameworks related to industrialization and manufacturing are strewn across different ministries, leading to limited coordination and implementation. Policy coherence, governance structures, and appropriate legislation are essential for creating a conducive environment for investment and sustainable local production. Policy development should ensure integration of science, technology and public health policy and creation of governance structures to coordinate and monitor implementation.¹³

13. **Inadequate regulatory oversight capacity:** The low maturity levels of national regulatory authorities is a barrier to ensuring access to quality, safe and efficacious locally manufactured and imported health products, including preventing market entry of substandard and falsified products. Limited investment in regulatory systems and inadequate legislative instruments have led to low maturity levels of NRAs, resulting in inadequate regulatory oversight.

14. **Insufficient investment in and coordination of research and development:** While there are specialized research and academic institutions in the African Region that conduct research and development, including the Noguchi Memorial Institute for Medical Research and the South African Medical Research Council, there is a need to invest in and ensure coordination and collaboration of research and development institutions to promote translational research and sustainable local production.

15. **Limited access to technology transfer:** Limited access to technology transfer remains an impediment to local manufacturers' ability to expand their product ranges into more complex therapeutic molecules, vaccines and other health technologies.

16. **Lack of coordination:** Several Member States are aiming to establish and scale up local production, with more than 10 countries planning to manufacture vaccines.¹⁴ However, a coordinated approach is needed to avoid duplication, allow for sharing of resources, and ensure the sustainability of local production initiatives across the African Region.

17. **Poor supply chain management and inefficient procurement:** There is a dearth of reliable market intelligence information in the African Region, which is detrimental to local production planning. Establishing and revitalizing regional pooled procurement mechanisms will address these information gaps, facilitate economies of scale, and long-term competitiveness of locally manufactured products.

18. **Poor access to finance:** Access to reasonably priced long-term financing is often unavailable. Compliance with cGMP is key for start-ups, business expansion, research and development, and facility modification. Government support through the reduction of upfront project and input costs,

¹² African Region partners (Spokes) are Kenya, Nigeria, Senegal, and South Africa. Kenya is yet to receive technology transfer training.

¹³ Fonseca DA, Massard E, Shadlen K, Bastos IF. Integrating science, technology, and health policies in Brazil: incremental change and public health professionals as reform agents. *Journal of Latin American Studies*. 2019; ISSN 0022-216X

¹⁴ Clinton Health Access Initiative. The African vaccine manufacturing ecosystem: Supply landscape and expansion plans; 2022 (<https://www.clintonhealthaccess.org/wp-content/uploads/2022/12/White-Paper-African-Vaccine-Manufacturing-Ecosystem.pdf>, accessed 8 February 2024)

such as customs duties on raw materials and equipment, as well as development of finance instruments, could help alleviate this challenge.

19. **Inadequate availability of skilled health technology workforce:** There is a lack of skilled health technology workforce with adequate manufacturing, distribution and regulatory knowledge and skills across the African Region. There are also workforce retention challenges. The cadres required include, among others, pharmacists, biomedical engineers, biological laboratory scientists and chemists. They require in-service industrial and regulatory training that is not offered by many universities in the Region. Government investment in ensuring technical workforce development and training is critical.

VISION, GOAL, OBJECTIVES, TARGETS AND MILESTONES

20. **Vision:** All people in the WHO African Region have equitable access to locally produced, quality, safe and efficacious medical products and health technologies.

21. **Goal:** Increased market share of locally produced medical products in the African Region.

22. Objectives:

- (a) To increase capacity for local production of quality, safe, efficacious and affordable medicines, vaccines, medical devices, and in vitro diagnostics to achieve at least 55% of the market share and 50% of vaccine doses produced locally by 2035.
- (b) To improve the ecosystem for local production of medical products through strengthening regulatory systems to have at least 15 national regulatory authorities achieving WHO Maturity Level 3 status by 2035.
- (c) To improve the skills of industry professionals through training to ensure that at least 9500 full-time equivalents¹⁵ are available by 2035.
- (d) To increase technology transfer partnerships and research and development linkages through facilitatory mechanisms and investments for at least 11 technology transfer partnerships and 250 research and development projects by 2035.
- (e) To implement at least three functional and sustainable regional pooled procurement mechanisms to support local production by 2035.

Regional targets

23. Governments to support local industry to ensure that by 2035:

- (a) Market share of locally produced medical products reaches 55%.
- (b) At least 50% of vaccine doses needed are manufactured in Africa.

Milestones by 2030

24. Member States of the African Region:

- (a) Invest in and support national regulatory authorities to ensure that at least 10 of them reach WHO Maturity Level 3.
- (b) Support at least 10 countries to have national manufacturers that:

¹⁵ A unit to measure employed persons in a way that makes them comparable although they may work different number of hours per week.

- 24.b.1. are certified to be current Good Manufacturing Practices (cGMP)-compliant by national regulatory authorities at WHO Maturity Level 3 or 4, or the African Medicines Agency,
- 24.b.2. and have achieved WHO prequalification for their products.
- (c) Support and increase the number of industry professionals trained and/or upskilled across different disciplines required for manufacturing to have at least 7000 full-time equivalents¹⁶ available.
 - (d) Strengthen technology transfer partnerships and linkages for at least 180 research and development projects and 8 technology transfer partnerships.
 - (e) Support the local industry and ensure that at least 30% of WHO pre-qualified vaccine doses needed are manufactured in Africa.
 - (f) Implement functional pooled procurement mechanisms to ensure cost-effective procurement of locally manufactured products in regional economic communities and at continental level.

GUIDING PRINCIPLES

25. **Ownership and governance:** Governments, regional economic communities, manufacturers, and development partners should coordinate efforts and put in place governance structures to monitor implementation plans to ensure success and ownership by all parties.
26. **Human rights and equitable access to medicines, vaccines and other health technologies:** All people of all ages regardless of gender, functional ability, ethnocultural background or socioeconomic status have the right to equitable access to medicines, vaccines and other health technologies.
27. **Holistic approaches:** Holistic approaches that address the manufacturing ecosystem at the country and regional levels should be adopted.
28. **Multisectoral and regional collaboration:** Strategies that are based on interministerial cooperation, private sector participation, and collaborative regional and subregional networks and partnerships, including public-private partnerships, should be implemented.
29. **Policies for sustainable local production establishments:** Policies that aim to incentivize investment and increase the competitiveness of local manufacturers should be implemented.¹⁷
30. **Continent-wide implementation of the African Continental Free Trade Area (AfCFTA):** This entails the implementation of national and regional legislation and procurement frameworks that are aligned with the tenets of the AfCFTA.
31. **Regulatory harmonization and strengthening:** Regulatory systems should be strengthened and harmonized, including the ratification of the AMA Treaty,¹⁸ to complement pooled procurement mechanisms and enhance intra-African trade.

¹⁶ A unit to measure employed persons in a way that makes them comparable although they may work different number of hours per week.

¹⁷ World Health Organization. Local Production for Access to Medical Products: Developing a Framework to Improve Public Health; 2011 (https://cdn.who.int/media/docs/default-source/medicines/local-production/local_production_policy_brief.pdf?sfvrsn=e4485e87_1&download=true, accessed 7 February 2024)

¹⁸ Health Policy Watch. See what countries have signed the African Medicines Agency Treaty (<https://healthpolicy-watch.news/african-medicines-agency-countdown/>, accessed 24 February 2024)

PRIORITY INTERVENTIONS AND ACTIONS

32. **Member States to develop and implement cohesive national and regional policies, legal frameworks and governance structures that include:**

- (a) National and regional policies and legal frameworks that create a conducive environment for investment and sustainable local production.
- (b) Development finance instruments (legal frameworks) such as seed capital, loans, equity investments and guarantees, including concessional loans, among others.
- (c) Provision of serviced land, implementation of tax holidays for start-ups and duty exemptions for imported inputs (raw materials and equipment).
- (d) Improving health financing strategies in the context of UHC to create market certainty.
- (e) Considering and implementing preferential local procurement schemes and pooled procurement mechanisms.
- (f) Setting up of manufacturing hubs within regional economic zones (REZs) for carefully selected health products, such as APIs, products for neglected tropical diseases and noncommunicable disease, among others, under regional organizations to avoid nationalistic interests and/or competition with established national manufacturers while ensuring access to quality, safe and affordable medicines, vaccines and other health technologies.
- (g) Regional governance structures responsible for the implementation and monitoring of health projects such as ECOWAS' West African Health Organization (WAHO). WAHO is a specialized institution of ECOWAS responsible for health issues¹⁹ and not a directorate within the ECOWAS Secretariat.
- (h) WHO and development partners advocating for and collaboratively supporting Member States in developing and implementing national and regional policies for sustainable local production.

33. **Strengthen regulatory systems:** Member States should implement institutional development plans (IDPs) to reach ML 3, review and enact appropriate legislation to ensure independent and functional NRAs, and legal frameworks for the harmonization and ratification of the AMA Treaty. Networks such as the African Vaccine Regulatory Forum (AVAREF) should be used for strengthening capacities, skills and expertise of the human resources needed for regulatory and ethics oversight. Member States and the WHO Secretariat should implement resolution WHA67.20²⁰ on regulatory system strengthening for medical products in collaboration with development partners.

34. **Increase investment in research and development:** Establish policies for public funding/subsidies to improve national and regional research and development capacities and translational research. Member States should review their research and development value chain to share resources, establish centres of excellence and create linkages between academic/research institutions, public health, industry, and global research institutions that will be beneficial to local manufacturing.

35. **Develop strategies for establishing and/or scaling up local production:** Such strategies should include the development of a regional local production road map or policy. A regional road map/strategy implementation plan may be developed with support from the WHO Regional Office for Africa, AUDA-NEPAD, development partners and other stakeholders. AUDA-NEPAD, WHO,

¹⁹ West African Health Organization (WAHO) Strategic Plan 2016 – 2020; accessed 03 March 2024

²⁰ World Health Assembly resolution WHA67.20 (2014) on Regulatory system strengthening for medical products.

industry and development partners should collaboratively review the PMPA and develop a road map for health product manufacturing in Africa.

36. **Enhance and facilitate technology transfer** through holistic approaches that address public health needs, intellectual property rights,²¹ facilitate the use of trade-related aspects of intellectual property rights (TRIPS)²² flexibilities,²³ and voluntary licensing. Opportunities for technology transfer of vaccines/biopharmaceuticals, medicines and other health technologies exist through the following initiatives:

- (a) WHO and partners' technology transfer hub in South Africa,
- (b) WHO Biomanufacturing Workforce Training Initiative,
- (c) WHO Health Technology Access Pool (HTAP),
- (d) African Development Bank's (AfDB's) African Pharmaceutical Technology Foundation (APTF),²⁴ and
- (e) Medicines Patent Pool (MPP)²⁵, as well as other development and research-based partners.

37. **Facilitate access to finance** through policies and legal frameworks/arrangements aimed at reducing the high risk-adjusted rate of interest charged by commercial banks. Implementing procurement policies that address external competition and market certainty, including off-take agreements, will complement these policies and further reduce the historically high-risk rating of local production projects by banks. Long-term finance is critical for pharmaceutical start-ups and established firms for expansion and plant modifications to ensure compliance with cGMP.

38. **Leverage global health initiatives** (such as the Lusaka Agenda: conclusions of the future of global health initiatives process) to facilitate sustainable in-country and external financing of health systems and coordinated approaches to regional manufacturing to address market and policy failures relevant to global health.

39. **Ensure availability of adequately skilled health workforce by:**

- (a) Investing in the development of adequately skilled health technology workforce for health product production and distribution, as well as regulation by increasing intake and output from training institutions and universities. This includes pharmacists, biomedical engineers, biological laboratory scientists, chemists, and technicians, among others.
- (b) Increasing opportunities for in-service upskilling and training for the various disciplines to ensure adequate numbers and skills are available to support the establishment and scaling up of local production.
- (c) WHO and technical partners providing support to Member States through training and capacity building to improve health workforce technical skills.

²¹ The legal rights given to the inventor or creator to protect his invention or creation for a certain period of time.

²² The TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement of the World Trade Organization (WTO) established minimum standards of protection that each government has to give to the intellectual property of fellow WTO members, thus limiting the former scope for flexible national approaches.

²³ These aim to permit developing and least-developed countries to use TRIPS-compatible norms in a manner that enables them to pursue their own public policies, either in specific fields like access to pharmaceutical products or protection of their biodiversity, or more generally, in establishing macroeconomic, institutional conditions that support economic development.

²⁴ African Development Bank Group. African Development Bank's Board approves landmark institution: Establishment of African Pharmaceutical Technology Foundation to transform Africa's pharmaceutical industry; 2022.

(<https://www.afdb.org/en/news-and-events/press-releases/african-development-banks-board-approves-landmark-institution-establishment-african-pharmaceutical-technology-foundation-transform-africas-pharmaceutical-industry-52727>; accessed 24 February 2024)

²⁵ Medicines Patent Pool (<https://medicinespatentpool.org/>, accessed 24 February 2024)

40. **Use pooled procurement mechanisms:** Establish and/or review regional pooled procurement mechanisms such as those of the Central African Economic and Monetary Community (CEMAC), EAC, SADC, ECOWAS/WAHO and Small Island Developing States (SIDS) to ensure that they are effective and efficient and that their policies support local production. Pooled procurement mechanisms and regulatory harmonization should complement each other.

41. **Ratify the African Continental Free Trade Area (AfCFTA) agreement:** Member States should sign and ratify the AfCFTA²⁶ agreement to create a single market for goods and services, enhance the movement of capital and ensure that country legislative instruments are reviewed in a timely fashion and amended to facilitate implementation of the AfCFTA agreement.²⁷

42. **Monitoring and evaluation:** WHO and Member States should establish a monitoring and reporting system on the implementation of this framework to evaluate progress towards the set milestones and targets.

ACTIONS PROPOSED

43. The Regional Committee is invited to examine and adopt the actions proposed.

²⁶ African Continental Free Trade Area. The AfCFTA: A new era of trade; 2023 (<https://au-afcfta.org/wp-content/uploads/2023/11/ENGLISH-FACTSHEET-BOOKLET-.pdf>, accessed 26 February 2024)

²⁷ The AfCFTA will create a continental market with a population of about 1.3 billion people, a combined GDP of approximately US\$ 3.4 trillion, enable African based manufacturers to have economies of scale and compete with the larger pharmaceuticals companies that export into Africa. As of January 2024, fifty-four African Union Member States had signed the AfCFTA Agreement and 47 (including 41 Member States of the WHO African Region) had ratified it. It should be noted that despite the positive aspects of the AfCFTA agreement mentioned above, balancing its possible negative impacts such as favoured treatment of larger manufacturers/countries over smaller manufacturers/countries and/or the creation of oligopolistic markets will have to be considered and addressed.