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Progress report on the implementation of the strategy for scaling up health innovations in the African Region

Information document

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Background

1. In 2020, the Seventieth session of the WHO Regional Committee for Africa adopted the Strategy for scaling up health innovations in the WHO African Region.[1,2] The strategy aims to foster Member States' commitment to accelerating health improvements by harnessing and scaling up innovations as key determinants for achieving universal health coverage (UHC) and health-related Sustainable Development Goals (SDGs).

2. The regional strategy envisions that by the end of 2025, eighty per cent of Member States will have developed national patent systems to fully reflect the flexibilities provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[3]; 75% will have established national regulatory mechanisms that fast-track the review of the science and maturity of innovations; and 60% will have a clear approach to engaging key stakeholders, including the private sector, to support the scaling up of locally developed health innovations.

3. This second progress report summarizes progress made in implementing the regional strategy and proposes the next steps for action**.**

Progress made/actions taken

4. Forty-three of the 47 Member States had patent systems in place either through regional organization membership or individual national offices as of 2024; twenty[4] are members of the African Regional Intellectual Property Organization (ARIPO), 17[5] are members of the Organisation Africaine de la Propriété Intellectuelle (OAPI), while six are neither members of ARIPO nor OAPI but have individual national patent offices.[6] Unlike ARIPO members, OAPI members do not have national patent offices, and patent registration is done through OAPI.

5. Although 80% of Member States were expected to have developed national patent systems to fully reflect TRIPS flexibilities, in early 2025, WHO assessed the implementation of key TRIPS flexibilities in the African Region and found that Member States' patent systems were not fully implementing key domains[7] of TRIPS flexibilities. Out of 29 Member States that are least-developed countries (LDCs), only six[8] had excluded pharmaceuticals from patentability, a key TRIPS flexibility available to LDCs. Many Member States were not conducting substantive patent examination, which is key to ensuring appropriate market competition and supporting local manufacturing development.

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1 Strategy for scaling up health innovations in the WHO African Region AFR/RC70/11: WHO Regional Office for Africa; 2020 (https://iris.who.int/handle/10665/333720, accessed 5 January 2023)

2 Adoption of the Strategy for scaling up health innovations in the WHO African Region AFR/RC70/R3: WHO Regional Office for Africa; 2020 (https://apps.who.int/iris/handle/10665/366052, accessed 5 January 2023)

3 Amendment of the TRIPS Agreement. (https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm, accessed January 2025)

4 Botswana, Cabo Verde, Eswatini, Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mauritius, Mozambique, Namibia, Rwanda, Sao Tome and Principe, Seychelles, Sierra Leone, United Republic of Tanzania, Uganda, Zambia and Zimbabwe

5 Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal and Togo.

6 Including Algeria, Angola, Ethiopia, Madagascar, Nigeria and South Africa.

7 Key domains for implementing TRIPS flexibilities include: implementation of the least-developed country transition period (where applicable), rigorous patentability criteria, effective mechanisms to challenge patents, international patent exhaustion to allow parallel importation, provision of exceptions for research and acts for obtaining regulatory approval, provision of sufficiently broad grounds for compulsory and government-use licensing, and development of competition laws and policies to promote public health.

8 Angola, Burundi, Liberia, Madagascar, Rwanda, and Uganda.

6. Although 75% of Member States were expected to have established national regulatory mechanisms that fast-track the review of the science and maturity of innovations, only seven[9] (15%) had achieved WHO Maturity Level 3[10] as of 2024.

7. To fast-track registration and improve access, WHO is supporting regional and continental regulatory strengthening and harmonization, and supports Member States to review biopharmaceutical product dossiers through the African Vaccine Regulatory Forum (AVAREF). WHO has developed a toolkit and monitoring and evaluation frameworks to facilitate integrated campaign digitization from lessons learnt across five pilot countries.[11]

8. By 2024, seventeen per cent of Member States had approaches for scaling up health innovations, far from the 60% target. Six Member States have been working on mechanisms to sustainably scale up health innovations to address prioritized health demands.[12] This includes mechanisms to evaluate health demands, source and match innovations, and sustainably integrate innovations into health systems strengthening initiatives.

9. The establishment of the WHO and partners' mRNA Technology Transfer Hub in South Africa marked a major milestone in advancing high-impact health innovations. By December 2024, three Member States[13] had successfully completed training in mRNA vaccine manufacturing technology at the Hub.

10. Furthermore, ongoing capacity-building initiatives are strengthening the Region’s health workforce to effectively adopt and implement new manufacturing technologies. These efforts include training on Good Manufacturing Practices (GMP) and the WHO prequalification processes, which are essential for quality assured health products.

Issues and challenges

11. Persisting challenges include limited implementation of TRIPS flexibilities, fragmented innovation activities, inadequate incentives and tools to assess both impact and risk of innovations, capacity gaps, limited public-private collaboration, and funding. Regulatory hurdles, lengthy partnership processes, and limited readiness for mRNA technology transfer further hinder the scaling up of health innovations.

Next steps

12. Member States should:

(a) review national laws and regional treaties to optimize use of TRIPS flexibilities for health and local production;
(b) scale up innovations by ensuring synergies across health system tiers, develop accountability agreements and sustainability plans that integrate human resource capacity;

[9] Ghana, Nigeria, Rwanda, Senegal, South Africa, United Republic of Tanzania and Zimbabwe.
[10] Stable, well-functioning and integrated regulatory system.
[11] Benin, Democratic Republic of the Congo, Kenya, Mozambique and Nigeria.
[12] Ethiopia, Ghana, Malawi, Nigeria, Somalia and Zimbabwe.
[13] Nigeria, Senegal, and South Africa.

(c) expedite finalization of partnership agreements for participation in the mRNA technology transfer initiative.

13. The WHO Secretariat and partners should:

(a) provide technical assistance to strengthen implementation of TRIPS flexibilities and prioritize the development of the WHO technology transfer strategy/road map in 2025.

(b) support Member States to strengthen their health innovation ecosystem and facilitate the local manufacturing of diagnostics.

(c) support health workforce capacity-building, including training on GMP and WHO prequalification processes, and encourage open science to foster collaboration in developing and manufacturing essential medical products.

14. The Regional Committee is invited to note this progress report and endorse the proposed next steps.