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Regional flagship initiative 1: Expanding equitable access to medical products

Executive summary

Safe, effective, quality and affordable essential medicines and vaccines are critical for effective health care, and spending on medicines and vaccines accordingly represents a high proportion of health expenditure. While there is some local manufacturing of essential medical products within the Eastern Mediterranean Region, most countries in the Region are heavily reliant on imports to obtain the medical products their people need. Not only does this dependency on foreign producers increase the risk of supply problems; it also means that much of the money spent on essential medical products – by individuals, governments and funders – benefits other economies, not the countries of the Region.

This flagship initiative proposed by WHO's Regional Director for the Eastern Mediterranean aims to enhance access to essential medical products by bolstering supply chain systems, promoting production and strengthening regulation **in** the Region **for** the Region. A new regional pooled procurement mechanism will strengthen accessibility and countries' bargaining position with manufacturers and reduce costs, while a programme of sustained technical support at country level will help build domestic capacities for production, distribution and regulation. As such, the initiative should support progress towards the health-related Sustainable Development Goals while also boosting economic growth in the Region.

Overall goals and specific objectives

This flagship initiative has three goals:

1. To reinforce the link between public health, economic growth and employment.
2. To ensure timely, affordable and equitable access to effective and safe medical products through reliable mechanisms, including a robust supply chain.
3. To support regional capacity for local manufacturing of essential medical products and strengthen national regulatory systems.

Specific objectives include to:

- ensure that medical products are readily available and accessible to all, regardless of their location or socioeconomic status, by enhancing supply chain operations;
- establish well-functioning regulatory systems that will ensure rigorous quality assurance and product safety;
- strengthen the resilience of the supply chain for essential medical products to minimize disruption during both acute and chronic emergencies through the development of comprehensive regional and national contingency plans;
- foster the sustainable and cost-effective local production of essential medical products, diversifying production among and within the Member States, leveraging production capacities to bolster the regional and national economies and ensuring health security at national and regional levels.

Background

Access to medicines and vaccines

Access to safe, effective, quality and affordable essential medicines and vaccines is crucial for achieving universal health coverage (UHC), as outlined in Sustainable Development Goal (SDG) target 3.8. However, around 2 billion people globally lack access to essential medicines, resulting in unnecessary suffering and deaths. Medicines and vaccines represent a significant proportion of health expenditure, ranging from 10–20% in developed countries to 20–60% in developing countries *(1)*.

Challenges in accessing medical products include high prices, weak regulatory mechanisms, the circulation of substandard products, shortages, inefficient procurement systems and high out-of-pocket costs. On average, one in eight people in the Region faces financial hardship due to health expenditure, with pharmaceutical costs making up 11–50% of total health spending. In some low- and lower middle-income countries, nearly 50% of out-of-pocket spending goes on medicines *(1)*.

Procurement and supply of medicines and vaccines

The Eastern Mediterranean Region relies heavily on importing medical products, including vaccines and new medicines *(2)*. Gulf Cooperation Council (GCC) member countries use pooled purchasing mechanisms for better prices, while many low- and middle-income countries face funding challenges and lack trained procurement staff. Most countries in the Region do not fully adhere to national standard treatment guidelines and essential medicine lists (EMLs).

Vaccine supply varies among countries in the Region by country income group. High-income countries have good access to new vaccines, while middle-income countries self-finance vaccine procurement and lower-income countries are supported by Gavi, the Vaccine Alliance. Since 2000, Gavi has worked to accelerate vaccine introduction by providing financial support and strengthening immunization systems *(3)*.

However, non-Gavi funded middle-income countries face challenges in vaccine procurement, such as high costs, wastage and limited access to new vaccines *(4)*. WHO assessments reveal gaps in the storage and distribution of medical products.

Countries such as Jordan and the United Arab Emirates have made improvements in warehouse facilities for medical products, with Jordan developing a plan to build and upgrade warehouses and the United Arab Emirates having a state-of-the-art facility built to international standards. Gavi, UNICEF and WHO support vaccine storage and management in low-income, Gavi-eligible countries.

Local production of medicines and vaccines

Many countries in the Region have invested in the local manufacturing of essential medicines, for example Pakistan, which has the most pharmaceutical companies, and the Islamic Republic of Iran, which produces 96% of its medicines locally. Jordan is notable for the high export value of its generic medicines. Only hepatitis C medicines, locally produced at different sites in Egypt and Morocco, have been prequalified by WHO. Countries such as Egypt, the Islamic Republic of Iran, Morocco, Pakistan and Tunisia are producing some biosimilars locally.

In terms of vaccine production in the Region, while Egypt, the Islamic Republic of Iran and Tunisia lead in this area, there exist challenges relating to quality issues and compliance with good manufacturing practices. Recent efforts to improve the situation include revamping facilities and seeking WHO prequalification.

Diversification of the production of molecules across countries is also essential to ensure a resilient regional supply chain, reduce dependence on other regions and enhance equitable access to life-saving medicines and medical supplies.

Regulatory systems

Since 1997, WHO has strengthened vaccine regulation through a national regulatory authority (NRA) assessment tool, replaced by the Global Benchmarking Tool (GBT) in 2018. The GBT evaluates regulatory systems, focusing on maturity levels from 1 (basic) to 4 (advanced). The goal is to achieve at least level 3, indicating a stable, integrated and well-functioning regulatory system.

The Egyptian Drug Authority reached maturity level 3 for vaccine regulation in March 2022, and the Saudi Food and Drug Authority achieved level 4 in October 2023. Lebanon, Morocco, Somalia, Tunisia and the United Arab Emirates are establishing independent regulatory authorities. The NRAs of the Islamic Republic of Iran, Jordan, Morocco, Oman, Tunisia and the United Arab Emirates are in the process of self-benchmarking, with formal assessments for some of them expected to be completed during 2025–2028.

Emergency and humanitarian settings

Countries with challenging conditions, such as Sudan, the Syrian Arab Republic and Yemen, have deteriorated infrastructure affecting the access of vulnerable groups to medical supplies. Local production has declined in these fragile and vulnerable settings and their regulatory systems have been negatively impacted. WHO's health emergency programme provides medication and kits using the Dubai hub for logistics, which plays a key role in the Region. WHO also has strategic hubs in Dakar and Nairobi.

WHO's work and achievements

WHO supports countries to implement good procurement practices through technical support and capacity-building. It updates its Model Lists of Essential Medicines every two years and has helped 19 of the Region's 22 countries and territories to develop or update their national medicines policies and EMLs *(1)*.

WHO also supports regulatory authorities through tailored training, peer learning and technical support, and regularly updates guidelines and manuals for regulatory systems, production and supply practices. It has established a unit for local production assistance, evaluated vaccine production ecosystems in the Islamic Republic of Iran, Tunisia and the United Arab Emirates, and provided support to vaccine producers in Egypt.

Link with GPW 14 and the regional strategic operational plan

This flagship initiative supports the regional strategic operational plan. Improving equitable access to medicines, vaccines and health technologies was a key focus of WHO's Thirteenth General Programme of Work (GPW 13) and will continue under its Fourteenth General Programme of Work (GPW 14) as a critical part of efforts to address global health challenges and enhance equity in health care.

Approach

Securing access to medicines and other medical products is a complex process requiring collaboration among various partners to ensure regulatory compliance, value for money and continuity of supply.

Efficient procurement involves strategically purchasing appropriate medical supplies at reasonable cost and ensuring timely delivery. A strong, healthy market is essential for establishing affordable, high-quality products and maintaining a sustainable supply.

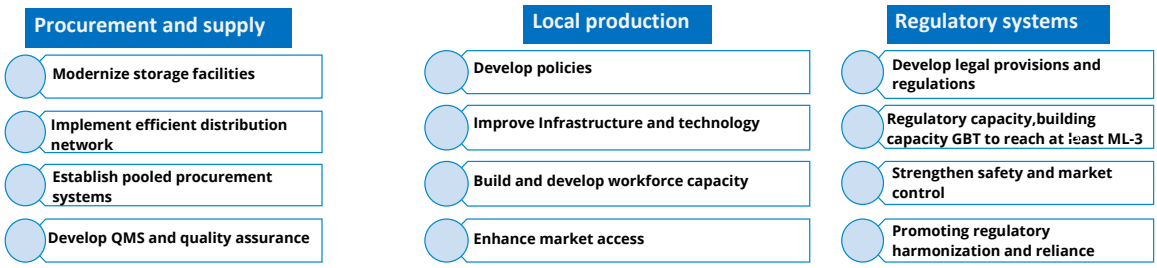

Fig. 1. Approaches used to ensure equitable and timely access to medical products in the Eastern Mediterranean Region

The procurement process should be comprehensive and strategic, incorporating practices such as avoiding repetitive purchases, consolidating orders for economies of scale, and streamlining procedures to reduce transaction and transport costs. Legislation and regulation must govern these systems to ensure the quality, safety and efficacy of medical products.

The WHO value chain for medical products aims to ensure equitable access to and delivery of medical products in low- and middle-income countries through all stages, including research, development, manufacturing, market registration, selection, pricing, reimbursement, procurement, supply, prescribing, dispensing, use and post-marketing surveillance.

To secure equitable and timely access to medical products and an efficient supply chain, this flagship initiative will focus on the following three crucial areas (see Fig. 1).

- **Procurement and supply chain systems:** strengthening country procurement and supply systems, including storage and distribution and establishing a regional procurement mechanism for medicines and other medical products/commodities.
- **Local production:** enhancing local manufacturing capacities.
- **Regulatory systems:** strengthening regulatory frameworks.

These areas are interrelated and need to be strengthened at both regional and country levels, and the approach needs to take account of each country's context, capacities and priorities.

The regional pooled procurement mechanism is a key component of this initiative. It will complement ongoing WHO support for implementing good procurement practices at the country level to help ensure an efficient supply of quality medical products. The mechanism aims to guarantee the availability of medical products, reduce costs and ensure equitable distribution to vulnerable populations, including refugees and internally displaced persons.

Promoting local manufacturing will help reduce reliance on global supply chains, mitigate risks from international disruption, and foster local economic growth through job creation and domestic product exports.

Strengthening regulatory systems is crucial for supporting quality production and improving procurement and supply processes, particularly within the pooled procurement framework.

The selection of medical products for possible coverage by pooled procurement is based on advice from technical units in the WHO Regional Office and from a regional pooled procurement expert consultation that took place in Cairo, Egypt, in September 2024, while taking into account the disease burden and specific public health needs in the Region, particularly among vulnerable populations, as well as cost-effectiveness and production shortages.

Products proposed for regional pooled procurement and local production include:

- high-priced medicines
- specific medicines and vaccines
- medications for common noncommunicable diseases (NCDs) such as hypertension and diabetes
- important health commodities for emergency preparedness and response, such as personal protective equipment and oxygen.

Key actions

1. Improve procurement and supply systems:

- assess supply systems in countries, from selection through procurement to storage and distribution;
- enhance supply chains by revamping and modernizing warehouses where needed and investing in logistics systems, cold chain management and digital technologies;
- support centralized country procurement systems to avoid fragmentation, reduce costs and ensure consistent supply;
- build capacity through ongoing training in procurement, supply and logistics management;
- promote regional cooperation and best practices in procurement and supply;
- establish a regional pooled procurement mechanism, as needed;
- partner with international organizations, donor agencies and global health initiatives for funding and technical support.

2. Promote local production:

- identify and support local manufacturers;
- promote and strategize the regional diversification of medical products among producers in the Region;
- provide technical support and facilitate partnerships to expand local production capacities and ensure diversification of products.

3. Strengthen regulatory systems:

- build regulatory capacity to ensure timely and effective regulation of medical products, mitigating substandard and falsified medical products;
- harmonize regulatory standards and promote reliance on well-functioning regulatory agencies;
- support regulatory authorities to achieve at least maturity level 3, especially in countries producing and exporting medical products;
- implement fast-track procedures for emergencies.

Theory of change

Inputs	Outputs	Outcomes	Impact
- Legal, policy and regulatory framework - Skilled and competent workforce, including regulatory experts, supply managers - Financial resources - Infrastructure: manufacturing plants, laboratories, warehouses, transportation means and distribution facilities - Technologies: equipment and technologies, NRA tools, supply chain management tools, digitalization systems and information management systems - Partnerships: collaboration with international organizations, regulatory agencies, pharmaceutical companies and nongovernmental organizations	- Harmonized regulations, implementation of regulatory principles and streamlined regulatory registration of medical products to improve accessibility of products - NRAs benchmarked against WHO GBT and institutional development plan (IDP) developed for achieving minimum maturity level 3 - Improved skills and knowledge of local production, regulatory and supply chain staff - Adequate manufacturing, laboratory, equipment, warehousing and distribution facilities according to good practice (GxP) requirements - Efficient local production, regulatory and supply chain processes - Effective quality control of procured medical products and market surveillance - Secured funding and investments supporting local production - Improved manufacturing capacity, increased availability and expanded portfolio - Expanded market for locally produced - Relationships with high-quality, reliable suppliers established - Effective logistics and distribution systems ensuring timely delivery - Monitoring and evaluation using defined key performance indicators and assessments to monitor the effectiveness of production, regulation, procurement and supply management systems	- Improved efficiency of local production, regulatory and supply chain processes - Increased availability of high-quality, affordable medical products - Reduced costs with economies of scale through pooled procurement - Stable and reliable systems for local production, regulation and supply management - Increased collaboration and solidarity among participating countries	- Growth through local manufacturing - Reduction in high burden diseases - Improved health outcomes - Positive contribution to achievement of SDGs

Assumptions

- Political stability and commitment to supporting improvements in local production, regulatory systems, procurement and supply management
- Availability of sufficient funding and technical support
- Willingness of international partners to collaborate and share information
- Supportive legal and policy environment
- Continued market demand for high-quality medical products

Risks

- Political or economic instability that may prevent/delay implementation
- Insufficient funding or delays in financial support
- Challenges in meeting international quality and regulatory standards
- Resistance to change or lack of cooperation among key stakeholders
- Supply chain disruption due to natural disasters or other emergencies and pandemics

Implementation plan

This flagship initiative will involve multiple interventions, requiring close collaboration among different technical departments within the WHO Regional Office, headquarters and country offices. Partners that can help mobilize resources for the three priority areas and advocate for and promote them will also be involved.

Activities	Implementation year				
	2024	2025	2026	2027	2028
Country procurement and supply systems					
Assess supply chain systems in countries	X	X	X		
Enhance supply chains to modernize warehouses and distribution network	X	X	X	X	X
Support establishment of national centralized procurement systems	X	X	X	X	X
Conduct training for strengthening procurement, supply and logistics management	X	X	X	X	X
Regional pooled procurement					
Obtain engagement of countries	X				
Set up the regional coordinating entity, defining its structure, functions, roles and responsibilities	X				
Conduct country needs assessment	X				
Develop a detailed action plan with timelines and responsibilities for each component of the pooled procurement and supply process	X				
Hold an expert consultation on the pooled procurement mechanism to identify the mechanism, model, country type and product type	X				
Establish a legal framework, such as a memorandum of understanding, and define the roles and responsibilities of all stakeholders		X			
Establish a committee with representatives from each participating country	X				
Conduct market analysis		X			
Develop procurement plans based on participating countries' needs		X			
Identify and engage with suppliers to negotiate contracts		X			
Implement regulatory harmonization	X	X	X	X	X
Allocate financial and human resources	X	X	X	X	X
Ensure necessary capacity-building for relevant staff	X	X	X	X	X
Develop guidelines and standard operation procedures	X	X			
Negotiate pricing and payment terms with the selected suppliers		X			
Map and conduct assessment of country warehouses	X	X	X	X	X
Implement efficient distribution system to ensure timely delivery of medical products	X	X	X	X	X
Conduct risk assessment		X	X	X	X
Develop risk management strategies		X	X	X	X
Conduct monitoring and evaluation	X	X	X	X	X
Local production					
Map local manufacturers	X	X			
Conduct a local production ecosystem assessment	X	X	X	X	X
Map research and development institutions	X	X			
Hold a regional meeting on the production of vaccine and other biologicals		X		X	
Conduct capacity-building on GXP and chemistry, manufacturing and controls (CMC), production and control technologies	X	X	X	X	X
Regulatory systems					
Provide technical support to support NRA self-benchmarking activity	X	X	X	X	X
Provide technical support to establish autonomous NRAs	X	X	X	X	X
Conduct pre-benchmarking and benchmarking missions	X	X	X	X	X
Follow-up on IDP implementation	X	X	X	X	X
Conduct capacity-building on regulatory functions	X	X	X	X	X
Hold a regional workshop on substandard and falsified (SF) medical products	X			X	
Monitoring and evaluation					
Develop and validate performance indicators	X				
Conduct monitoring and evaluation	X	X	X	X	X

Table 1. Main deliverables of the flagship initiative by year 2024–2028

	2024	2025	2026	2027	2028
Procurement and supply system	**Regional pooled procurement**				
	- Selection of included medical products - Assessment of country supply chain - One country with modernized central warehouse	- Harmonization of pooled procurement requirements - Pilot phase - Assessment of country supply chain - Two countries with central modernized warehouses	- Expansion of the pilot phase - Three countries with modernized central warehouses	- Pooled procurement of medicines/vaccines implemented - Four countries with modernized central warehouses	- Pooled procurement of medicines/vaccines applicable to countries that joined the regional pooled procurement initiative - Five countries with modernized central warehouses
Local production	**Promoting local production**				
	- Mapping of local manufacturers	- Three countries manufacturing quality-assured products	- Five countries manufacturing quality-assured products	- Six countries manufacturing quality-assured products	- Seven countries manufacturing quality-assured products
Regulatory system	**Strengthening NRAs**				
	- Seven independent country NRAs - One NRA at ML-3 - One NRA at ML-4	- Nine independent country NRAs - Two NRAs at ML-3 - One NRA at ML-4	- 11 independent country NRAs - Four NRAs at ML-3 - One NRA listed in the WLA	- 13 independent country NRAs - Five NRAs at ML-3 - One NRA listed in the WLA	- 13 independent country NRAs - Five NRAs at ML-3 - One NRA at ML-4 - One NRA listed in the WLA

Expected outcomes and results

Key targets

The main deliverables to be accomplished by 2028 are shown in the following Table 1. The selection of deliverables takes into account the priorities and existing capacity/resources of the WHO team at regional level, as well as country priorities, context, resources and capacities.

Monitoring and evaluation

Continuous monitoring will help to identify and address deviation from the implementation plan, to avoid delays and disruption in access to medical products. Three main sets of indicators are proposed:

- timeliness and completeness of the different steps of the pooled procurement process;
- number of products procured, volume of local production, number of autonomous regulatory agencies, number of NRAs that have established institutional development plans, number of NRAs that have achieved maturity level 3 (ML-3), maturity level 4 (ML-4) and WHO-Listed Authority (WLA) status;
- cost-savings and product availability.

Budget

Currently, human and financial resources are limited.

The initiative requires extensive technical coordination by various units at regional and country levels, which necessitates additional staff and financial resources (see Table 2).

Table 2. Funding required to implement the flagship initiative

Item	2024	2025	2026	2027	2028	Total
	Budget (US$)					
Procurement and supply systems including regional pooled procurement						
P4 technical officer	100 000	400 000	400 000	400 000	400 000	1 700 000
Logistic officers (3)	150 000	350 000	350 000	350 000	350 000	1 550 000
Setting up a regional networking and steering committee	20 000	50 000	50 000	50 000	50 000	220 000
High-level meetings/policy dialogue	–	100 000	100 000	100 000	100 000	400 000
Seed funding for country-level work (including assessment and capacity-building in supply chain management)	100 000	700 000	700 000	800 000	800 000	3 100 000
Local production						
P4 technical officer	100 000	400 000	400 000	400 000	400 000	1 700 000
Setting up a regional networking and steering committee	20 000	60 000	60 000	60 000	60 000	260 000
High-level meetings/policy dialogue	–	130 000	150 000	150 000	200 000	630 000
Seed funding for country-level work	–	700 000	700 000	800 000	800 000	3 000 000
Regulatory systems						
P4 technical officer	100 000	400 000	400 000	400 000	400 000	1 700 000
Setting up a regional networking and steering committee	–	120 000	120 000	150 000	150 000	540 000
High-level meetings/policy dialogue	50 000	100 000	100 000	100 000	100 000	450 000
Seed funding for country-level work (including assessment and capacity-building in regulatory systems)	–	1 000 000	1000 000	1 500 000	1 500 000	5 000 000
Total						**20 250 000**

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[1] All references were accessed on 27 August 2024.

Annex 1. Regional pooled procurement mechanism

Establishing the regional pooled procurement mechanism requires a well-coordinated approach, strong governance, effective management, dedicated, skilled staff and funds *(1)* (Fig. A1).

It could be established as follows:

- Establish a steering committee to ensure the coordination of the process.
- Select and agree on the pooled procurement mechanism (model).
- Establish a legal framework such as a memorandum of understanding and define the roles and responsibilities of all stakeholders.
- Establish a committee with representatives from each participating country.
- Conduct market analysis to understand the supply and demand, pricing trends and potential suppliers, as well their capacities, to ensure they can meet the pooled procurement needs.
- Develop procurement plans based on participating countries' needs, and definie the process for tendering, evaluation and contract management.
- Identify and engage with suppliers to negotiate contracts and build long-term agreements.
- Implement a quality assurance system, including guidelines and procedures for bidding, selection and awarding contracts.
- Implement regulatory harmonization to ensure regulatory requirements are harmonized and product specifications (both technical and programmatic) are standardized.
- Allocate financial and human resources.
- Ensure capacity-building through regular training of the workforce involved in pooled procurement.
- Negotiate pricing and payment terms with the selected suppliers.
- Ensure appropriate storage areas to maintain the quality, safety and efficacy of medical products.
- Implement an efficient distribution system to ensure the timely delivery of medical products.
- Develop risk management strategies (contingency plans) to avoid shortages and discontinuity in access to medical products.

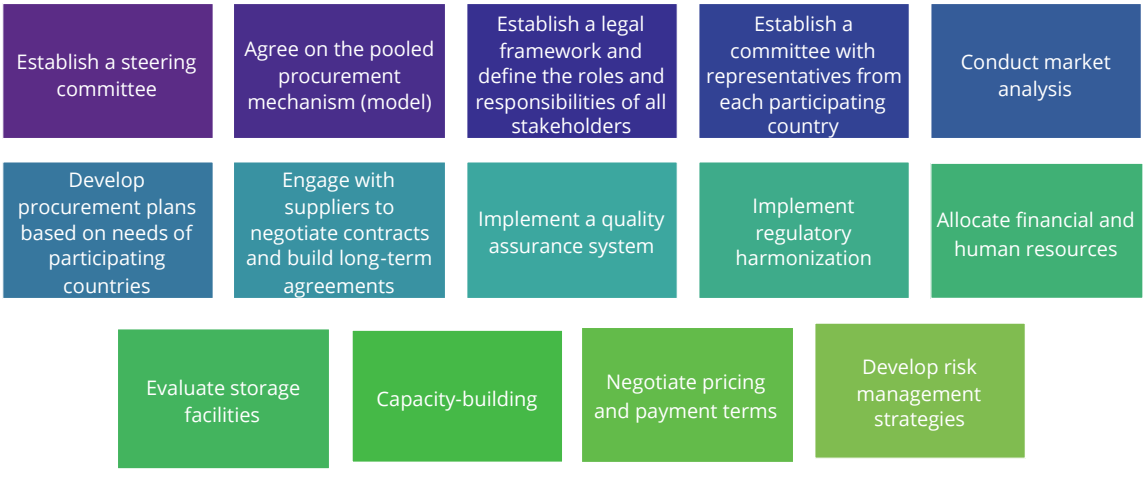

Fig. A1. Strategy for pooled procurement mechnsism in the Eastern Mediterranean Region *(1)*

There are four models of pooled procurement, reflecting different levels of collaboration (2):

- **informed buying**: **countries** purchase products individually based on shared information about prices and suppliers;
- **coordinated informed buying**: **countries** conduct organized market research, share performance information and monitor prices;
- **group contracting**: countries follow a unified process for supplier selection, price negotiation and awarding contracts;
- **central contracting and procurement**: all processes are managed by a central procurement agent on behalf of participating countries.

The key steps in pooled procurement include:

1. assessing country willingness and ability to cooperate;
2. assessing country needs;
3. developing databases on pricing, patent status and supplier qualifications;
4. harmonizing regulations and administrative processes;
5. piloting with a few countries and few products before scaling up;
6. applying WHO quality policies for procurement, ensuring products meet technical and programmatic standards *(3)*.

If Members States endorse this initiative and the establishment of regional pooled procurement of selected products, it is proposed that the pooled procurement process will be initiated through a pilot phase with one vaccine and possibly one medicine.

The main partners may include:

- government agencies (ministries of health, NRAs);
- international organizations (Global Fund to Fight AIDS, Tuberculosis and Malaria, UNICEF, United Nations Industrial Development Organization);
- regional organizations (Africa Centres for Disease Control and Prevention, African Union);
- nongovernmental organizations and humanitarian agencies (International Red Cross and Red Crescent Movement, Médecins Sans Frontières);
- donor agencies and financial institutions (Islamic Development Bank, World Bank);
- the private sector (manufacturers, logistics companies);
- universities and research institutes.

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