



Progress report on the regional strategy to improve access to medicines and vaccines in the Eastern Mediterranean Region, 2020–2030, including lessons from the COVID-19 pandemic

Introduction

1. In October 2020, the 67th session of the Regional Committee adopted resolution EM/RC67/R.2 endorsing the Regional strategy to improve access to medicines and vaccines in the Eastern Mediterranean Region, 2020–2030, including lessons from the COVID-19 pandemic, and its framework for action.
2. In recognition of the role of access to safe and quality-assured medicines and vaccines in benefitting 1 billion more people with universal health coverage and in protecting 1 billion more people from health emergencies, implementation of the framework has focused on eight strategic objectives: national policies for medicines and vaccines; sustainable funding; availability and affordability of medicines and vaccines; efficient supply systems; strengthening national regulatory authorities (NRAs); rational use of medicines; local production of quality medicines and vaccines; and strong partnership frameworks.
3. This report provides a progress update on implementation by Member States and WHO during the first two years of the 10-year framework, as well as challenges and the way forward.

Progress update

National policies for medicines and vaccines

4. Support was provided to Member States for the development, adoption and implementation of comprehensive national medicines and vaccines policies and essential medicines lists, and to strengthen evidence-based selection using health technology assessment methodology. The Islamic Republic of Iran, Jordan, Pakistan and Syrian Arab Republic were supported to update their national essential medicines list to include the antibiotic AWaRe (Access, Watch or Reserve) categories. Lebanon developed a national pharmaceutical policy in May 2022.
5. WHO has been supporting assessments of the pharmaceutical sector in Member States. Data for pharmaceutical country profiles have been collected from Afghanistan, Iraq, Lebanon, Oman, Pakistan, Palestine and the Syrian Arab Republic, based on a survey developed to measure key aspects of the pharmaceutical sector, to systematically monitor the progress in efforts to improve access to essential medicines. A paper on pharmaceutical regulations in Iraq was published in the Eastern Mediterranean Health Journal in October 2021.¹

¹ Pharmaceutical regulations in Iraq: from medicine approval to post-marketing. Al-Jumaili AA, Younus MM, Kannan YJA, Nooruldeen ZE, Al-Nuseirat A. East Mediterr Health J. 2021;27(10):1007-1015. doi:10.26719/emhj.21.025.

Sustainable funding

6. WHO continued to advocate for Member States to secure, within national priorities, sufficient domestic public funding for essential medicines and vaccines through improved public financial management.
7. WHO contributed to the dissemination of policies and best practices related to equitable medicines financing as well as efficient and effective financial management.

Availability and affordability of medicines and vaccines

8. The *WHO guideline on country pharmaceutical pricing policies* was issued in 2020 to assist Member States in managing pharmaceutical prices. WHO is working to promote information exchange on medicine prices between countries in the Eastern Mediterranean Region. WHO conducted a vaccine pricing analysis as part of the vaccine procurement modernization agenda in Jordan.
9. WHO organized the third global Fair Pricing Forum in April 2021 to discuss the affordability and transparency of prices and costs relating to health products and to activate support for countries to achieve more affordable and fairer access to pharmaceutical products during the COVID-19 pandemic and beyond. Saudi Arabia will be hosting the fourth Fair Pricing Forum in 2023.

Efficient supply systems

10. WHO supported the establishment of policies and good practices, as well as capacity-building, for improving governance, efficiency and quality of procurement and supply-chain management, both in ordinary and emergency situations. Jordan and Libya conducted an assessment of their national medical supply systems.
11. WHO provided technical support to ensure that national essential medicines lists are revised periodically to align with the WHO Model List of Essential Medicines, consider emerging health priorities and reflect updates in the evidence and its application in procurement and development of hospital and primary care formularies.

Regulatory systems

12. WHO has been supporting countries to strengthen their NRAs to ensure the quality, safety and efficacy of medicines, vaccines and other medical products. Technical support was provided to Egypt for the evaluation of vaccine production capacities to embark on production of COVID-19 vaccines for the country and also targeting the Eastern Mediterranean Region and some African countries. Jordan, Oman, Pakistan and Saudi Arabia were supported to establish NRA institutional development plans and to set up a roadmap for benchmarking. Technical sessions on the NRA benchmarking concept and self-benchmarking exercise were organized for regulators of all Member States to strengthen the regulatory systems in countries for ensuring effective implementation of vaccines regulation, as well as regulation of other medicines and biological products.
13. The Egyptian Drug Authority succeeded in reaching maturity level 3 for vaccines regulation (locally produced and imported) which means that it is recognized as a stable, well-functioning and integrated regulatory system and is included in the “transitional” WHO Listed Authorities (tWLA) list. A regulatory authority moves from the tWLA list to the permanent WLA list upon successful completion of the WLA evaluation process.

14. WHO supported national pharmacovigilance training workshops in Jordan and Yemen to promote the reporting of adverse drug reactions, adverse events following immunization, medication errors and lack of therapeutic efficacy. Kuwait, Lebanon and Libya became full members of the WHO Programme for International Drug Monitoring, increasing the number of members from the Region to 16 countries. Fourteen countries in the Region reported adverse events following immunization with COVID-19 vaccines to the global database. Iraq, Lebanon and Morocco made significant progress in the reporting of individual case safety reports of COVID-19 vaccines into WHO's VigiBase. In addition, a regional network for pharmacovigilance was launched in January 2022.

15. As part of efforts to engage countries in the Collaborative Registration Procedure (CRP), WHO conducted a series of meetings to raise awareness and increase knowledge of authorities on the CRP mechanisms, processes, requirements and available tools, as well as to support implementation of the CRP in countries. Several Member States of the Region showed interest in being part of this initiative.

16. WHO conducted several virtual meetings on the safety and regulatory preparedness of COVID-19 vaccines. All countries in the Region were able to grant emergency use authorization for the first vaccines allocated through the COVAX Facility within 15 days. By the April 2022, countries had granted 215 regulatory approvals.

Rational use of medicines

17. WHO has provided support to Member States to establish medicines and therapeutics committees at the health facility level in order to improve rational use of medicines and national medicines supply systems.

18. WHO conducted virtual training workshops on national antimicrobial consumption surveillance and hospital antimicrobial consumption monitoring. Afghanistan, Egypt, Iran (Islamic Republic of), Iraq, Jordan, Kuwait, Oman, Pakistan, Palestine, Qatar, Somalia, Syrian Arab Republic, Tunisia and Yemen have enrolled in the Global Antimicrobial Resistance and Use Surveillance System (GLASS), and Egypt, Iran (Islamic Republic of), Iraq, Jordan and Tunisia shared their national antimicrobial consumption data.

Local production of quality medicines and vaccines

19. The current interest in local production of medicines and vaccines is significant, both as a strategy to improve access to medicines and vaccines and for industrial and economic development. The Regional Office conducted: a training workshop on key enabling factors for successful local production and supply of quality-assured medical products; a regional technical workshop on vaccine manufacturing, with the Coalition for Epidemic Preparedness Innovations (CEPI); and an expert consultation to develop a regional vaccine production strategy with a focus on COVID-19 vaccines. A regional strategy to increase vaccine production in the Eastern Mediterranean Region is now being drafted. Egypt, Islamic Republic of Iran, Pakistan and United Arab Emirates are manufacturing COVID-19 vaccines, and eight COVID-19 vaccines were produced in 2021. Egypt, Pakistan and Tunisia were also chosen as recipients of mRNA technology.

Establishing partnerships and improving collaboration

20. WHO organized the Eastern Mediterranean Drug Regulatory Authorities Conference (EMDRAC), bringing together NRAs from around the Region as well as regulatory leaders from regional and international organizations, to enhance cooperation between the regulatory authorities, exchange experiences and promote regulatory harmonization initiatives. Heads and senior staff of NRAs from 19 countries participated and shared approaches to strengthen the marketing authorization process, improve supply chain management and monitor adverse events following COVID-19 vaccination. The NRAs agreed

on specific recommendations for strengthening the regulation of medical products in the Region including a regional plan of action, as part of the global response to COVID-19.

Challenges

21. A major challenge in the implementation of the regional strategy is insufficient human and financial resources in addition to a lack of long-term sustainable funding, particularly for human resources.
22. Likewise, a lack of adequate resources at the regional level has affected the provision of sustained and coordinated technical support to Member States for improving access to medicines and vaccines.
23. Inadequate attention is given to the role of access to affordable and quality-assured medicines and vaccines in achieving universal health coverage and protecting people in emergencies.
24. COVID-19 negatively affected the implementation of some planned activities, as the focus of the health ministries, NRAs and country offices was on pandemic response.
25. There is inadequate or ineffective coordination between NRAs and ministries of health in some countries.
26. The protracted conflicts and instability in some countries of the Eastern Mediterranean Region is an ongoing challenge to implementation of the proposed activities of the strategy.

The way forward

27. Member States are urged to continue to take action to accelerate implementation of the regional strategy to improve access to medicines and vaccines at the national level to ensure the availability of high-quality medicines and vaccines.
28. Member States need to ensure and maintain availability of and access to a priority list of medicines and health products as a basic human right and ensure that medicines and health products for priority health conditions are not abruptly halted.
29. Joint or pooled procurement at the national, regional and global levels has proved an effective means to secure lower prices and offers promise for expansion. WHO can support the scaling up of collaborative approaches for strategic procurement and Member States are urged to establish a regional pooled procurement/joint purchasing mechanism for specific medicines and vaccines.
30. Member States are urged to promote and support the scale up of production of safe, effective, quality and affordable medicines and vaccines.
31. WHO will continue to provide Member States with sustained and coordinated guidance as well as technical support to scale up implementation of the regional strategy, and will provide a report on progress at the 71st session of the Regional Committee in 2024.