



Regional strategy to improve access to medicines and vaccines in the Eastern Mediterranean, 2020–2030, including lessons from the COVID-19 pandemic

Executive summary

1. The 2030 Agenda for Sustainable Development identified access to safe, effective, quality and affordable essential medicines and vaccines as central to the achievement of universal health coverage, in target 3.8 of the Sustainable Development Goals (SDGs). Access to medicines and vaccines continues to be a challenge worldwide, mainly for low- and middle-income countries. The key difficulties include lack of good governance and regulation, high prices, shortages and stockouts, limited collaborations and, more recently, the impacts of the coronavirus disease 2019 (COVID-19) pandemic. In the WHO Eastern Mediterranean Region, the prevailing political, emergency and humanitarian situations in several countries impose further demand- and supply-side challenges to equitable access.
2. Although national medicines policies and essential medicines lists exist in most countries of the Region, collaborative action is required on a regional level to ensure that the needs of patients and populations can be met. Access to medicines and vaccines in the Region varies among countries, depending on their income level and allocation of domestic resources to medicine and vaccine procurement. Even in higher-income countries, medicine and vaccine procurement and supply management systems need to be strengthened to prevent recurrent stockouts and shortages. In addition, very few vaccine manufacturers exist in the Region, with limited production capacity and no prequalified vaccines.
3. COVID-19 has imposed additional barriers to access to medicines and vaccines, including the impact of lockdowns on the supply chain which led to shortages of medical products and increases in price. On the other hand, potential COVID-19 vaccines may provide an opportunity to strengthen national immunization programmes. To support the development and equitable distribution of COVID-19 products, WHO and partners established the Access to COVID-19 Tools (ACT) Accelerator initiative in April 2020. In addition, the COVID-19 Global Vaccine Access (COVAX) Facility was established under the leadership of Gavi, the Vaccine Alliance, with the aim of having 2 billion doses of vaccine distributed equitably across the world by the end of 2021.
4. WHO has been at the forefront of the movement to improve the safety, efficacy, availability and affordability of medicines and vaccines, as mandated by successive World Health Assembly and Regional Committee resolutions. This paper presents a new regional strategy for the Eastern Mediterranean Region which has been developed to address the barriers to accessing medicines and vaccines, and to guide countries in strengthening their national health systems over the next 10 years. It takes into account the lessons learned from the international and regional responses to COVID-19, and supports the commitments made in WHO's Thirteenth General Programme of Work (GPW 13) and the Region's Vision 2023 to expand universal health coverage, respond to emergencies and promote health.
5. The regional strategy aims to ensure that everyone in the Eastern Mediterranean Region has access to the quality essential medicines and vaccines they need, without suffering financial hardship, by 2030. It advances eight strategic objectives related to: updating and implementing national policies for medicines and vaccines; securing adequate and sustainable funding; ensuring the availability of medicines and vaccines at fair and affordable prices; establishing efficient supply systems; strengthening national regulatory authorities; ensuring appropriate use of medicines; promoting research and development as well as local production; and establishing a strong partnership framework. The strategy also proposes a set of priority actions for Member States, WHO and development partners to pursue, with associated outcomes/deliverables. Prominent among these are: securing sufficient domestic public funding for essential medicines and vaccines; reviewing national vaccination schedules and essential medicines lists; reviewing medicine and vaccine procurement

systems; promoting local production; establishing a regional pooled procurement/joint purchasing arrangement; sharing information on prices; and establishing partnerships and improving collaboration.

6. The Regional Committee is invited to endorse the proposed regional strategy to improve access to medicines and vaccines in the Eastern Mediterranean, 2020–2030.

Introduction

7. The 2030 Agenda for Sustainable Development identified access to safe, effective, quality and affordable essential medicines and vaccines as central to the achievement of universal health coverage, in target 3.8 of the Sustainable Development Goals (SDGs) (1). Access to medicines and vaccines continues to be a challenge both globally and in the Eastern Mediterranean Region, mainly in low- and middle-income countries. It is estimated that around 2 billion people worldwide do not have access to essential medicines (2), resulting in suffering, prolonged illnesses, needless disabilities and preventable deaths.

8. Medicines,¹ including vaccines, account for a significant share of health spending, ranging from 10–20% in developed countries to 20–60% in developing countries (2). In addition, medicines constitute a large proportion of out-of-pocket expenditures in most countries (3), undermining access and increasing the risk of financial hardship (4–6). A recent study on vaccine financing estimated that vaccine expenditures account for a small proportion (less than 2%) of total health spending in middle-income countries (7).

9. In the Eastern Mediterranean Region, information available from 10 high- and middle-income countries suggests that total pharmaceutical expenditures represent 11–50% of total health spending. On the other hand, in some low- and lower middle-income countries close to 50% of out-of-pocket spending goes on medicines: 54% in Afghanistan (2017) (8) and 43% in Pakistan (2015–2016) (9).

10. Vaccines included in national immunization programmes are provided free of charge in public facilities; and while vaccination through the private health sector is expanding, the public sector continues to provide most vaccination services. In the Region, WHO estimates that two out of every three children with no access to pneumococcal and rotavirus vaccines live in middle-income countries.

11. Lack of good governance, high prices and limited collaborations are among the key challenges to effective and equitable access to medicines and vaccines in the Region. The prevailing political and humanitarian challenges – including conflicts, occupation and political sanctions – impose further demand- and supply-side challenges, undermining access to medicines and vaccines in several countries of the Region.

12. The coronavirus disease 2019 (COVID-19) pandemic² has brought additional challenges, with some medicines including hydroxychloroquine, dexamethasone, selected antivirals and antimicrobials, as well as vitamins (10–13), becoming unavailable due to off-label dispensing and stockpiling.³ In addition, the pandemic has contributed to the proliferation of substandard and falsified medicines;⁴ and impacted the

¹ Medicines are defined as any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient. While WHO works to promote affordable access to medical devices and other medical products, which are crucial for a well-functioning health system and for the pursuit of universal health coverage, the focus in this paper is on medicines and vaccines. According to WHO definitions, the terms medicine and pharmaceutical are used interchangeably.

² WHO declared COVID-19 a public health emergency of international concern on 30 January 2020 and a pandemic on 11 March 2020.

³ This is the case for dexamethasone and other critical sedation medicines used in intensive care units, such as midazolam and propofol, which are needed for intubated patients and those who are placed on mechanical ventilation. See: Silverman E. A new Covid-19 problem: shortages of medicines needed for placing patients on ventilators [website]. Boston MA: STAT News; 2020 (<https://www.statnews.com/pharmalot/2020/03/31/a-new-covid-19-problem-shortages-of-medicines-needed-for-placing-patients-on-ventilators>, accessed 7 September 2020).

⁴ Interpol reported that nearly 20 million illicit pharmaceutical items including anaesthetics, analgesics, antimalarial medicines, benzodiazepines and corticosteroids, as well as personal protective equipment, were taken off the market in the Middle East and North Africa in February and March 2020 (<https://www.interpol.int/en/News-and-Events/News/2020/Operation-in-the-Middle-East-and-North-Africa-targets-pharmaceutical-crime>, accessed 7 September 2020).

production and exportation of non-COVID-19 medicines by limiting importation of raw materials and interrupting country supply chains (14). On the other hand, promising COVID-19 vaccine candidates may provide an opportunity to strengthen national immunization programmes as well as improving pandemic response.

13. Responding to concern about the limited access to medicines and vaccines expressed by Member States at the 66th session of the Regional Committee, and considering the acute need to inform regional and national efforts to enhance access to COVID-19-related medicines and vaccines, the WHO Regional Office for the Eastern Mediterranean embarked on developing a regional strategy for improving access to medicines and vaccines in the Eastern Mediterranean, 2020–2030, including lessons from the COVID-19 pandemic.

14. The regional strategy aims to complement the WHO global Road map for access to medicines, vaccines and other health products 2019–2023 (15), while benefiting from multiple global and regional commitments,¹ including resolution WHA73.1 of the Seventy-third World Health Assembly on timely access for all to quality, safe, efficacious and affordable COVID-19-related diagnostics, therapeutics, medicines and vaccines, by addressing their fair distribution, on the path to universal health coverage and health security. The strategy translates the commitments made in WHO's Thirteenth General Programme of Work (GPW 13) and the regional Vision 2023, by supporting the three strategic priorities of expanding universal health coverage, responding to emergencies and promoting health. The regional strategy builds on global and regional work and was informed by consultation with Member States, international and regional experts, and development partners. It provides a comprehensive agenda to enhance access to medicines and vaccines in countries of the Eastern Mediterranean Region over the next 10 years.

Access to medicines and vaccines: regional situation

Analytical framework

15. Several analytical frameworks have been used to monitor access to medicines and vaccines.² These were developed prior to the ongoing pandemic and hence are unlikely to capture the complexity of access to medicines and vaccines in the context of COVID-19. This paper therefore employs a health systems-based framework (16) to monitor access to medicines and vaccines, as related to SDG target 3.8 on universal health coverage and target 3.b on research and development. This analytical framework is based on the following seven attributes:

- evidence-based selection
- sustainable financing
- affordable prices
- procurement and supply management system
- regulation and quality assurance
- rational use
- trade and production.

¹ Including: EM/RC33/R.10 (1986) on rational use; EM/RC33/R.9 (1986), EM/RC49/R.9 (2002) and EM/RC49/R.13 (2002) on traditional medicines; EM/RC44/R.5 (1997) on appropriate health technology; EM/RC45/R.9 (1998) on regional self-reliance in the production of essential drugs and vaccines; EM/RC47/R.7 (2000) on health technology and trade; EM/RC49/R.8 on antimicrobial resistance and rational use of antimicrobial agents; EM/RC51/R.10 (2004) on vaccine development, accessibility and availability; EM/RC53/R.12 (2006) on regional guidelines on stability testing of active substances and pharmaceutical products; EM/RC54/R.8 (2007) on medicine prices and access to medicines; WHA65.19 (2012) on substandard and falsified medical products; WHA67.22 (2014) on access to essential medicines; WHA69.20 (2016) on promoting innovation; and WHA69.25 (2016) on addressing the global shortage of medicines and vaccines (among others).

² Historically, access to medicines and vaccines was analysed under four dimensions: availability, affordability, geographical accessibility and cultural acceptability (the 4As), with some frameworks adding quality. In 2004, WHO proposed a four-part framework based on: rational selection and use, affordable prices, sustainable financing and reliable supply systems. The Lancet Commission on Essential Medicines Policies grouped the challenges to accessing essential medicines under: (a) inadequate financing; (b) unaffordability; (c) poor quality and safety; (d) inappropriate use; (e) and failure to produce and supply new essential medicines that target unmet disease burden or offer more effective outcomes.

16. The status of access to medicines and vaccines in the Region and the impact of COVID-19 in countries was assessed using a self-administered questionnaire and an extensive literature search. The findings were reviewed at an online consultation with Member States, experts and development partners. This culminated in the regional goal, and associated strategic objectives and priority actions, to improve access to medicines and vaccines in the Eastern Mediterranean.

Regional challenges

17. Despite the existence of national medicines policies and essential medicines lists in most countries of the Region, several barriers to access to medicines remain, including: high prices of new medical products; weak regulatory mechanisms; increased circulation of substandard and falsified medical products; shortages and stockouts of essential medicines; inefficient procurement and supply management systems; low capacity to conduct health technology assessment of medical products; limited information sharing on prices; weak collaboration with industry in the private sector; high out-of-pocket spending; and irrational use of medicines, contributing to rising antimicrobial resistance.

18. Regarding access to vaccines, countries of the Region fall into three groups based on their income level. First, a group of six high-income countries has adequate access to most new vaccines with limited financial challenges. These countries have succeeded in establishing a joint medicine and vaccine procurement system with unique tendering which works relatively well to limit competition, despite some incidents of delayed delivery and stockouts mostly attributed to small volumes. Nine middle-income countries also fully self-finance their vaccine requirements. This group faces the challenge of insufficient allocation of domestic resources to vaccine procurement, resulting in delayed introduction of new life-saving vaccines despite evidence on their cost-effectiveness. The third group comprises seven low-income countries which are eligible for assistance from Gavi, the Vaccine Alliance. Gavi provides financial support to procure new and underutilized vaccines, with a small co-financing component, as well as cash support for health system strengthening and improving the cold chain for immunization services.

19. Inefficiency in vaccine procurement and management remains a challenge in the first two groups, resulting in procurement at excessive prices, high vaccine wastage and recurrent stockouts. Gavi-eligible countries face other challenges including: high dependency on donors; failure to fulfil co-finance commitments in a timely manner; inability to mobilize resources to procure vaccines not supported by Gavi; frequent stockouts; inadequate vaccine procurement systems; and inefficient use of the dedicated cash component to improve the immunization system. Paradoxically, access to conjugate pneumococcal and rotavirus vaccines in the Gavi-eligible countries is higher than that in Gavi-ineligible middle-income countries.

20. At present, there are around five vaccine producers in the Region, with limited production capacity and no prequalified vaccines. Over the last 20 years, most regional manufacturers of vaccines suspended their activities due to noncompliance with good manufacturing practice requirements.

21. Annex 1 provides further details on the key issues related to access to medicines and vaccines in the Eastern Mediterranean Region.

WHO response

22. WHO has been supporting Member States of the Region to improve access to medicines and vaccines. In 1993, WHO established the Eastern Mediterranean Drug Regulatory Authorities Conference (EMDRAC) as an independent regional platform to promote effective regulation of medical products and enhance networking, cooperation and information sharing between regulatory authorities. Since then, 15 countries have undergone official and unofficial assessment of their national regulatory authorities (NRAs). WHO also supported countries to strengthen their pharmacovigilance systems, with 13 countries becoming full members in the WHO Programme for International Drug Monitoring and six countries becoming associate members. Support was also provided as part of the Good Governance for Medicines programme in 16 Member States. In the area of supply chain management, technical assistance was provided to strengthen national procurement

and distribution systems. Support was also provided in the areas of health technology assessment, local production, market surveillance and herbal medicine.

23. WHO support to improve access to vaccines goes primarily on strengthening planning and building capacity. In addition, in 2009, to improve purchasing capacity in the Region, countries expressed strong interest in establishing a regional pooled vaccine procurement (PVP) mechanism¹ with support from WHO. Accordingly, three consecutive Regional Committee resolutions were endorsed between 2011 and 2013.²

24. Based on a feasibility study conducted by WHO, the PVP system was to be established in two phases. Phase 1 consisted of collaboration between the WHO Regional Office and the United Nations Children's Fund (UNICEF) Supply Division to provide procurement services to middle-income countries for pneumococcal conjugate, rotavirus and human papilloma virus vaccines, starting from the fourth quarter of 2013. This was achieved, and a few middle-income countries used UNICEF's procurement system to acquire new vaccines. In phase 2, starting 2015, the Regional Office was requested to establish a central procurement unit to procure all requested vaccines and immunization supplies and coordinate the financial flow of the PVP system, with the ultimate aim of establishing a mechanism similar to the Pan American Health Organization's revolving fund. WHO, in collaboration with UNICEF and the Pan American Health Organization, developed the requisite legal agreements, the policy and operational documents detailing the necessary regulating roles and responsibilities of various entities, and the operating procedures and principles. However, despite the original request from Member States and efforts by WHO over several years, the PVP initiative did not progress. The key challenges were lack of adequate political commitment, conflict of interest at country level, failure to mobilize seed funds to initiate the PVP system, internal financial procedures that prevented upfront payment by countries, and reluctance of countries to join without prior information on vaccine prices.

25. Technical assistance has been provided to all vaccine manufacturers to meet WHO recommendations and international requirements. For example, the Pasteur Institutes in the Islamic Republic of Iran and Tunisia modernized their facilities and resumed vaccine production to meet the minimum national needs for some vaccines. Furthermore, WHO assessed NRAs as functional for vaccine regulation in Egypt and the Islamic Republic of Iran and as functional for vaccine procurement in some countries, such as Morocco and Tunisia. In addition, technical support is provided to inform decision-making about introducing appropriate new vaccines according to global recommendations and local epidemiological profiles.

26. Recently, WHO support was extended to countries in the Region in the area of similar biotherapeutic medicines, of which there has been a significant increase in local production (six countries) and importation of biosimilars from different emerging markets. However, issues around regulatory evaluation and market authorization of biosimilars need to be addressed.

27. The African Union is supporting the establishment of the African Medicine Agency (AMA) to ensure harmonization of medical regulation throughout Africa. AMA will enter into effect once 15 African Member States ratify the AMA Treaty. Morocco and Tunisia signed the AMA Treaty in 2019; however, none of the seven countries of the Region located in Africa have ratified the Treaty as yet.

¹ The potential benefits of such a mechanism include: better financial sustainability and supply security for immunization programmes; improved access to new and underutilized vaccines, with assured quality at competitive prices; economies of scale through combined volume orders from participating countries; reduced procurement and operational costs such as forecasting, supplier and product search, tendering, bid solicitation, bid awarding, contracting, purchase ordering and other related procedures; more accurate and reliable forecasts of short-term and long-term demands to suppliers to match supply and demand; increased responsiveness of countries to outbreaks and emergencies through operational and financial buffer mechanisms; enhanced information exchange and learning between countries regarding vaccine pipeline and market, vaccine procurement, legislation, regulation, and supply chain products and activities; and transparency, credibility and accountability of procurement activities.

² EM/RC58/R.5 (2011); EM/RC59/R.1 (2012); and EM/RC60/R1 (2013).

Access to medicines and vaccines in the context of COVID-19

28. COVID-19 has imposed additional challenges regarding access to medicines and vaccines, both globally and in the Region. Around 80% of all active pharmaceutical ingredients, as well as many finished medicines and health commodities, are manufactured in China and India. Lockdowns and closures impacted the supply chain for health products by negatively affecting air cargo, sea freight and land transportation, slowing down local production. This led to shortages of medicines and vaccines and increases in price.

29. Several treatments and vaccines are being explored to combat COVID-19. WHO, in collaboration with partners, created the Solidarity Response Fund to support studies on COVID-19 (17), mainly on four repurposed medicines: chloroquine/hydroxychloroquine; remdesivir; lopinavir/ritonavir; and interferon beta-1a. Over 100 countries in all six WHO regions joined or expressed interest in joining the trials. In parallel, the Institut national de la santé et de la recherche médicale (Inserm) in Paris, France, launched a European clinical trial named DISCOVERY with the intention of enrolling 3100 patients in seven European countries. To date, 32 teaching hospitals in France and two in Luxembourg are taking part in the study (18).

30. Most repurposed medicines have been shown to be ineffective against COVID-19,¹ except for remdesivir which demonstrated modest impact in shortening hospital stays (but no effect in reducing mortality) of hospitalized patients (19). In addition, WHO recommends systemic corticosteroids rather than no corticosteroids for the treatment of patients with severe and critical COVID-19.² As of 9 September 2020, over 180 vaccine candidates are at some stage of development; of these, 35 are in human trials of which nine are in phase III. Only seven countries in the Eastern Mediterranean Region are enrolled in human trials of COVID-19 vaccine.³

31. Many health programmes, notably malaria and HIV, have been affected by medicine shortages due to the increased demand for chloroquine/hydroxychloroquine and lopinavir/ritonavir for use in COVID-19 patients. In addition, several countries in the Region reported blood supply shortages due to a decrease in blood collection and donation following lockdowns, as well as reluctance of blood donors due to fear of infection. Plasma from recovered COVID-19 patients has been used either in trials (for example in Egypt, the Islamic Republic of Iran and Pakistan) or for compassionate treatment (where it was reported in some instances to be sold at very high prices). Governments responded by stocking up on COVID-19-related products and rationing other medicines. This was in addition to pressure being exercised on suppliers, who became overwhelmed with huge concomitant demands.

32. To support the development and equitable distribution of COVID-19 products (including tests, treatments and vaccines), WHO, Gavi, civil society organizations, philanthropists, businesses and other partners established the Access to COVID-19 Tools (ACT) Accelerator initiative in April 2020. In addition, and to guarantee rapid, fair and equitable access to COVID-19 vaccines worldwide, the COVID-19 Global Vaccine Access (COVAX) Facility was established, whereby WHO would advise on policy and allocation decisions, the Coalition for Epidemic Preparedness Innovations (CEPI) would be responsible for the development and manufacturing of effective vaccines, and Gavi would be responsible for procurement and delivery. The aim is to have 2 billion doses of vaccine distributed equitably around the world by the end of 2021.

33. The COVAX Facility currently includes nine vaccines of various types, including two new technology platforms: RNA and DNA vaccines. Seventy-five countries, including 21 countries in the Eastern Mediterranean Region, submitted expressions of interest in the COVAX Facility, joining another 90 countries who would be supported by the COVAX Advance Market Commitment (AMC).

¹ The hydroxychloroquine and lopinavir/ritonavir arms were discontinued based on recommendations from the Solidarity trial's International Steering Committee.

² Update as per WHO guidelines issued on 2 September 2020, <https://www.who.int/publications/i/item/WHO-2019-nCoV-Corticosteroids-2020.1>.

³ Morocco is currently conducting a controlled trial; Oman and Tunisia asked for WHO support in joining the Solidarity trial; Egypt will be starting a controlled trial after signing an agreement with Sinovac, China.

34. WHO is developing a global allocation framework with Member States for distributing the vaccines and other COVID-19 tools, based on the principle of fair and equitable access. Concurrently, support will continue to Member States to build national manufacturing capabilities and to buy supply ahead of time. Table 1 provides a summary of WHO and development partner support to increase access to COVID-19 vaccines, in alignment with the seven attributes of access to medicines and vaccines.

Table 1. WHO and partner support to countries for access to COVID-19 vaccines

Attribute	Support from WHO and development partners
Evidence-based selection	WHO-coordinated Solidarity vaccine trials: six countries of the Eastern Mediterranean Region joined the Solidarity call to action (Egypt, Lebanon, Oman, Pakistan, Sudan and Tunisia).
Sustainable financing	COVAX Facility for financing, including agreements with manufacturers unified across the full scope of participating countries. Gavi COVAX AMC/official development assistance (ODA) financing to support low-income and lower middle-income countries, and Gavi COVAX/procurement support with cost recovery for upper middle-income and high-income countries (ODA funding to be used only to support low-income and lower middle-income countries). WHO working with countries on national financing policy to ensure active involvement in the COVAX Facility.
Affordable prices	COVAX AMC to enable price/volume reduction. Economy of scale through pooled procurement of vaccines by the COVAX Facility. Eleven countries in the Eastern Mediterranean Region are eligible for AMC support and 10 countries have expressed interest in participating in the COVAX Facility.
Procurement and supply management system	Target: to procure 2 billion doses of COVID-19 vaccine globally, so that vaccines are made available to countries participating in the COVAX Facility by the end of 2021. Centrally coordinated procurement of selected vaccines and supply through UNICEF's Supply Division. Allocation of vaccines among countries participating in the COVAX Facility under the principles of proportional distribution; gradual rolling allocation according to availability of the vaccine of choice and adaptation to country contexts.
Regulation and quality assurance	COVAX Facility payments to manufacturers conditional on WHO prequalification of candidate vaccines. WHO support to NRAs for emergency approval. WHO guidelines on evaluation of the quality, efficacy and safety of DNA vaccines updated and adopted by the WHO Expert Committee on Biological Standards. WHO guidance document on evaluation of the quality, efficacy and safety of RNA vaccines under development. Vaccine safety preparedness plan to be developed, as part of vaccine deployment plans.
Rational use	Every country to decide priority target groups for vaccination, according to their context. Strategic allocation of limited products to maximize health impact. Strategic Advisory Group of Experts (SAGE) on Immunization working group on COVID-19 vaccines to provide detailed guidance on rational use of available vaccines. Three priority target groups to reduce mortality and protect health care workers: health care workers (~1% of the global population); elderly population >65 years (~8% of the global population); and high-risk adults with comorbidities (~15% of the global population).
Trade and production	Advance payment to manufacturers to accelerate investments and prevent delay. Technology transfers to vaccine manufacturers in developing countries. Down payment for upfront advance purchase agreements.

Regional strategy to improve access to medicines and vaccines in the Eastern Mediterranean: goal, strategic objectives and priority actions

35. Improving access to medicines and vaccines is a common good and is critical for achieving universal health coverage. It requires a comprehensive health systems approach and strong partnerships, aligned with national development policies and supported by legal and regulatory frameworks that address all stages of the medicines and vaccines life-cycle and value chain.¹ Building regional medicine and vaccine production capacity, enhancing procurement arrangements and ensuring effective supply chains all need to be part of the regional health security agenda, and require regional solidarity between different countries and with stakeholders to leverage available technical capacities and financial capabilities.

Goal and strategic objectives

36. The goal underpinning the regional strategy is: Everyone in the Eastern Mediterranean Region has access to the quality essential medicines and vaccines they need, without suffering financial hardship, by 2030.

37. This goal will be realized through the eight strategic objectives set out below.

- Strategic objective 1: Formulate, update, implement and monitor comprehensive national policies for medicines and vaccines, while ensuring all stakeholders' commitment to implementation.
- Strategic objective 2: Secure adequate and sustainable funding, and effective financing mechanisms with necessary flexibilities, to ensure regular supply of essential medicines and vaccines, with emphasis on priority diseases and vulnerable populations.
- Strategic objective 3: Ensure the availability of medicines and vaccines at fair and affordable prices in both the public and private sectors.
- Strategic objective 4: Establish efficient supply systems to ensure the flow of quality essential medicines and vaccines on a regular basis and in sufficient quantities to all levels of the distribution chain.
- Strategic objective 5: Strengthen national regulatory authorities to ensure the quality, safety and efficacy of medicines and vaccines.
- Strategic objective 6: Ensure the appropriate use of medicines by health professionals and consumers.
- Strategic objective 7: Promote research and development and the local production of quality medicines and vaccines that meet public health needs.
- Strategic objective 8: Establish a strong partnership framework with all relevant sectors and stakeholders, leveraging the comparative advantages of each, to promote the regional and national agenda of improving access to medicines and vaccines for all.

Priority actions

38. At the operational level and in order to pursue the strategic objectives, a set of priority actions are needed by Member States, WHO and other development partners. Annex 2 presents the new regional strategy. It details priority actions for countries, in the immediate and medium terms, as well as supporting actions for WHO and concrete deliverables to be achieved over the lifespan of the strategy (2020–2030).

39. The proposed priority actions are directed towards identified challenges as based on the situation analysis, and are in line with recommendations made in various WHO guidance documents.² Some priority actions are proposed based on lessons learned from successful country experiences, such as the Gulf

¹ This includes: (a) needs-based research, development and innovation; (b) manufacturing processes and systems that ensure quality products as well as managing the problem of substandard and falsified medicines; (c) public health-oriented intellectual property and trade policies; (d) selection, pricing and reimbursement policies; (e) integrity and efficiency of procurement and supply; and (f) appropriate prescribing and use.

² These include: WHO guidelines for good regulatory practices; aide-memoire for strengthening national regulatory authorities; a framework on local production for access to medical products; operational principles for good pharmaceutical procurement guidelines on good distribution practice and storage of essential medicines; aide-memoire, manual and global benchmarking tools on strengthening national regulatory authorities; and manual for strengthening the AEFI surveillance system.

Cooperation Council Joint Procurement Program, health technology assessment institutions in the Islamic Republic of Iran and Tunisia, and Egypt's and Pakistan's experiences of making direct-acting antivirals available at affordable prices. The proposed priority actions are to be adapted to countries' political and socioeconomic environment and capacity. While there is a need to work on all the priority actions, the most urgent actions for Member States are set out below.

- Secure sufficient domestic public funding for essential medicines and vaccines, through improved financial management and innovative ways to mobilize domestic and external resources.
- Review national vaccination schedules and essential medicines lists to ensure evidence-based inclusion of highly effective and cost-effective medicines and vaccines in publicly financed benefit packages. For immunization, this requires improving decision-making capacity through the establishment or strengthening of independent national immunization technical advisory groups (NITAGs) to ensure regular updates of national vaccination schedules and the introduction of life-saving vaccines.
- Review medicine and vaccine procurement systems to ensure the procurement of quality-assured products at the most affordable price.
- Promote local production of medicines and vaccines by developing an enabling business and regulatory environment and providing necessary market incentives.
- Establish a regional pooled procurement/joint purchasing arrangement for vaccines and specific types of essential medicines, including biosimilars.
- Share information on medicine and vaccine prices and procurement with other Member States through WHO's Market Information for Access to Vaccines (MI4A) initiative.¹
- Establish partnerships and improve collaboration and information exchange with international and national partners, other countries and all stakeholders including industry and research institutions.

Implementation and monitoring of the regional strategy

40. The successful implementation of the regional strategy at country level requires: high-level political commitment supported by relevant policies and reforms; independent NITAGs and functioning health technology assessment institutions; harmonization of legislation and regulatory procedures including a national essential medicines list, standard treatment guidelines and registration procedures; and adequate and predictable financial resources for the regular and timely allocation of funds and for managing payments. Successful implementation of the strategy remains a joint responsibility that requires concerted efforts and coordinated actions by all stakeholders, both national and international, under the leadership of the ministry of health and the NRA. This could be facilitated by establishing a national technical committee to follow up implementation of the identified priority actions and to monitor progress in access to medicines and vaccines.

41. To support the implementation of the regional strategy, WHO will:

- establish a regional technical advisory group to provide recommendations on measures to improve access to essential medicines and vaccines in the Region, and support the use of relevant indicators for measuring access to essential medicines and vaccines;
- assist NRAs in strengthening their regulatory systems to secure an efficient supply management system, meeting good manufacturing practice requirements for local production of medicines and vaccines;
- support assessments of the pharmaceutical sector and implementation of regular monitoring and evaluation systems for measuring the impact of interventions on access, quality and proper use of medicines and vaccines.

¹ MI4A: Market Information for Access to Vaccines [website]. Geneva: World Health Organization; 2019 (https://www.who.int/immunization/programmes_systems/procurement/mi4a/platform, accessed 9 September 2020).

Conclusion

42. Access to essential medicines and vaccines continues to be a challenge in many Member States of the Eastern Mediterranean Region. WHO has been at the forefront of the movement to improve the safety, efficacy, availability and affordability of medicines, as mandated by successive World Health Assembly and Regional Committee resolutions. The new regional strategy has been developed to address the challenges identified in providing access to safe, effective, affordable and sustainable supplies of medicines and vaccines, and to guide countries in strengthening their national health systems over the period 2020–2030. This will ensure the continuity, sufficiency, sustainability and security of national supplies of safe, efficacious and effective medicines and vaccines to meet the needs of patients and populations. WHO will continue to provide the needed support to Member States in their efforts to improve access to medicines and vaccines.

43. The Regional Committee is invited to endorse the proposed regional strategy to improve access to medicines and vaccines in Eastern Mediterranean, 2020–2030.

References

1. Resolution 70/1. Transforming our world: the 2030 Agenda for Sustainable Development. In: Seventieth session of the United Nations General Assembly 2015. New York: United Nations; 2015 (A/RES/70/1; https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_RES_70_1_E.pdf, accessed 7 September 2020).
2. Access to medicines: making market forces serve. In: Ten years in public health 2007–2017: report by Dr Margaret Chan, Director-General. Geneva: World Health Organization; 2017 (<https://apps.who.int/iris/bitstream/handle/10665/255355/9789241512442-eng.pdf?sequence=1>, accessed 17 September 2020).
3. Sum G, Hone T, Atun R, Millett C, Suhrcke M, Mahal A et al. Multimorbidity and out-of-pocket expenditure on medicines: a systematic review. *BMJ Glob Health*. 2018;3(1):e000505. doi: [10.1136/bmjgh-2017-000505](https://doi.org/10.1136/bmjgh-2017-000505).
4. Bigdeli M, Laing R, Tomson G, Babar Z. Medicines and universal health coverage: challenges and opportunities. *J Pharm Policy Pract*. 2015;8(1):8. doi: [10.1186/s40545-015-0028-4](https://doi.org/10.1186/s40545-015-0028-4).
5. Wagner AK, Graves AJ, Reiss SK, LeCates R, Zhang F, Ross-Degnan D. Access to care and medicines, burden of health care expenditures, and risk protection: results from the World Health Survey. *Health Policy*. 2011;100(2–3):151–8. DOI: [10.1016/j.healthpol.2010.08.004](https://doi.org/10.1016/j.healthpol.2010.08.004).
6. Xu K, Evans DB, Kawabata K, Zeramdini R, Klavus J, Murray CJ. Household catastrophic health expenditure: a multicountry analysis. *Lancet* 2003;362(9378):111e7. DOI: [10.1016/S0140-6736\(03\)13861-5](https://doi.org/10.1016/S0140-6736(03)13861-5).
7. Onishchenko K, Hill S, Wasserman M, Jones C, Moffatt M, Ruff L et al. Trends in vaccine investment in middle income countries. *Hum Vaccin Immunother*. 2019;15(10):2378–85. doi: [10.1080/21645515.2019.1589287](https://doi.org/10.1080/21645515.2019.1589287)
8. Afghanistan national health accounts with disease accounts, 2017. Kabul: Islamic Republic of Afghanistan, Ministry of Public Health; 2019 (https://moph.gov.af/sites/default/files/2019-09/Afghanistan%20National%20Health%20Accounts%202017_Final%20%28Annexes%29%2024-8-2019%20-min.pdf, accessed 17 September 2020).
9. National health accounts Pakistan 2015-16. Islamabad: Government of Pakistan, Pakistan Bureau of Statistics; 2018 (http://www.pbs.gov.pk/sites/default/files/NHA-Pakistan%202015-16%20Report_0.pdf, accessed 17 September 2020).
10. B Mehta, J Salmon, S Ibrahim. Potential shortages of hydroxychloroquine for patients with lupus during the coronavirus disease 2019 pandemic. *JAMA Health Forum*. 2020 (<https://jamanetwork.com/channels/health-forum/fullarticle/2764607>, accessed 7 September 2020).

11. Soliman M. Egypt's drug authority warns against hoarding and overdosing on vitamins to fight coronavirus. Ahramonline. 4 June 2020 (<http://english.ahram.org.eg/NewsContent/1/64/371506/Egypt/Politics-/Egypts-drug-authority-warns-against-hoarding-and-o.aspx>, accessed 7 September 2020).
12. Zhang D. Demand for dexamethasone rises after study finds COVID-19 benefits, FDA data shows. USA TODAY. 2 July 2020 (<https://www.usatoday.com/story/news/2020/07/02/coronavirus-drug-cheap-steroid-shortage-after-increased-demand/5355016002/>, accessed 7 September 2020).
13. Drug shortages list [website]. Bethesda MD: American Society of Health-System Pharmacists (ASHP); 2020 (<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortages-List?page=CurrentShortages>, accessed 7 September 2020).
14. Choo EK, Rajkumar SV. Medication shortages during the COVID-19 crisis: what we must do. Mayo Clin Proc. 2020;95(6):1112–5. doi: [10.1016/j.mayocp.2020.04.001](https://doi.org/10.1016/j.mayocp.2020.04.001).
15. A/72/17. Access to medicines and vaccines. Report by the Director-General. In: Seventy-second World Health Assembly, Geneva, 20–28 May 2019. Geneva: World Health Organization; 2019 (http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_17-en.pdf, accessed 7 September 2020).
16. Bigdeli M, Jacobs B, Tomson G, Laing R, Ghaffar A, Dujardin B et al. Access to medicines from a health system perspective. Health Policy Plan. 2013;28:692–704. DOI: [10.1093/heapol/czs108](https://doi.org/10.1093/heapol/czs108).
17. WHO, UN Foundation and Partners launch first-of-its-kind COVID-19 Solidarity Response Fund [website]. Geneva: World Health Organization; 2020 (<https://www.who.int/news-room/detail/13-03-2020-who-un-foundation-and-partners-launch-first-of-its-kind-covid-19-solidarity-response-fund>, accessed 7 September 2020).
18. Eynde JJV. COVID-19: an update about the Discovery clinical trial. Pharmaceuticals (Basel). 2020;13(5):98. doi: [10.3390/ph13050098](https://doi.org/10.3390/ph13050098).
19. Beigel JH, Tomashek KM, Dodd LE, Mehta AK, Zingman BS, Kalil AC et al. Remdesivir for the treatment of Covid-19 – preliminary report. N Engl J Med. 2020;NEJMoa2007764. DOI: [10.1056/NEJMoa2007764](https://doi.org/10.1056/NEJMoa2007764).

Annex 1. Key issues in access to medicines and vaccines in the Eastern Mediterranean Region

Attribute	Key issues
1. Evidence-based selection	<p>National medicines policies exist in 18 Member States, but they are incomplete: none of the policies has provisions on regulatory procedures and supply chain management in cases of emergency, pandemics and crisis situations, and they all lack relevant implementation plans.</p> <p>National immunization technical advisory group (NITAG) not established in one country and not fully functioning in six countries.</p> <p>National essential medicines lists exist in 20 Member States and were updated in the last five years by 16 Member States; half of these were updated in the last two years.</p> <p>Sixteen countries are at different stages of implementation of WHO's Good Governance for Medicines programme.</p> <p>Two Member States have national institutions responsible for health technology assessment.</p> <p>All countries have developed emergency clinical guidelines for treatment of COVID-19 patients.</p>
2. Sustainable financing	<p>Many countries lack staff with financing and budgeting skills relevant to medicine and vaccine management, contributing to inefficient financial planning and management.</p> <p>Information on public and private funding for essential medicines and vaccines is not readily available.</p> <p>Financial and economic analysis of medicine expenditures to promote efficiency and cost-effective financing is rarely undertaken.</p> <p>Many countries indicate that medicines are provided free of charge to those who cannot afford them, including children under five, pregnant women and elderly people.</p> <p>Co-payments or user fees are imposed for medicines in 11 countries.</p>
3. Affordable prices	<p>WHO/Health Action International surveys have been conducted in 12 countries.</p> <p>There are large price variations between countries for identical medical products.</p> <p>The average availability of selected generic essential medicines in the public sector is less than 32%.</p> <p>Legal or regulatory provisions on medicine pricing exist in most Member States, with most countries using external reference pricing combined with mark-up regulations.</p> <p>Half of countries impose duties on imported active pharmaceutical ingredients and on imported finished products.</p> <p>Provisions for tax exemptions or waivers for pharmaceuticals and health products are in place in eight countries.</p> <p>Sharing of information on prices of medicines between countries is limited.</p> <p>Due to the COVID-19 pandemic, prices of certain medical products have risen due to increase in demand and decrease in supply.</p>
4. Procurement and supply management system	<p>Most countries report that public sector requests for tender documents and public sector tender awards are made publicly available.</p> <p>Procurement in many countries is restricted to prequalified suppliers.</p> <p>Most countries operate a central medical store at the national level.</p> <p>Medicine supply is not based on national standard treatment guidelines in the majority of countries.</p> <p>At the hospital level, forecasting and quantification are done manually (paper-based).</p> <p>Calculation of needs is done using the past consumption method only and no automated calculation tools are used.</p> <p>Many countries indicate that government funding is insufficient and/or released irregularly, and that the number of trained procurement staff is inadequate.</p> <p>National guidelines on good distribution practice exist in fewer than half of all countries, and licensing authorities are very uncommon.</p> <p>Gulf Cooperation Council countries participate effectively in a joint procurement programme that leads to lower prices and increased quality of medical products.</p> <p>UNICEF Supply Division procurement services procure vaccines for Gavi-eligible countries, using WHO prequalified products at favourable prices, benefiting eight countries.</p> <p>During the COVID-19 pandemic, regular supply chains of essential medicines and health technologies were disrupted, as multiple countries needed to procure the same products at the same time.</p>

Attribute	Key issues
5. Regulation and quality assurance	<p>National regulatory authorities (NRAs) have been instituted in most countries; however, NRA performance could be improved.</p> <p>Most NRAs carry out marketing authorization, import control, licensing, inspection and market control, laboratory testing and quality control, pharmacovigilance and clinical trial control.</p> <p>Twenty countries have legal provisions for marketing authorization of all pharmaceutical products available on the market.</p> <p>All countries have adopted conventions related to controlled medicines and have laws to control narcotic and psychotropic substance use.</p> <p>Thirteen countries are full members of the WHO Programme for International Drug Monitoring, and six countries are associate members.</p> <p>Many NRAs lack capacities and expertise to assess and regulate biological products.</p> <p>Half of countries do not have national guidelines on good manufacturing practice.</p>
6. Rational use	<p>Nineteen countries have legal provisions that prohibit dispensing prescription medicines without a prescription; however, 16 countries report that antibiotics are sometimes sold over the counter.</p> <p>Ten countries allow the substitution of generic equivalents at the point of dispensing.</p> <p>Eight countries in the Region have a public or independently funded national medicines information centre providing information on medicines to prescribers, dispensers and consumers.</p> <p>Six countries have data on national antimicrobial consumption.</p> <p>Twelve countries have regulations requiring hospitals to organize/develop pharmacy and therapeutics committees.</p> <p>Nine countries have mandatory continuing education for medical doctors and pharmacists that includes rational use of medicines.</p> <p>Self-medication in relation to prevention/treatment of COVID-19 is occurring in some countries.</p>
7. Trade and production	<p>Fourteen countries are members of the World Trade Organization and 21 countries are members of the World Intellectual Property Organization.</p> <p>Most countries have established legal provisions for pharmaceuticals patenting.</p> <p>Twenty countries have domestic pharmaceutical manufacturers; the total number of licensed pharmaceutical manufacturers in the Region is 1249, of which 666 are in Pakistan.</p> <p>Capacity for research and development is limited and it is only possible in four countries.</p> <p>Six countries produce biopharmaceuticals.</p> <p>Six countries have the capacity to produce active pharmaceutical ingredients.</p> <p>The percentage of locally manufactured medicines as a share of total market volume is highest in the Islamic Republic of Iran and, until recently, the Syrian Arab Republic: 96% and 90%, respectively.</p> <p>Few countries export significantly more pharmaceuticals than they import; in 2019, Jordan had the highest pharmaceutical products export value at US\$ 636 882 464 million.</p> <p>No country can meet its public health needs in terms of production of vaccines.</p> <p>Four countries are under some form of sanctions which indirectly prevent them from improving their medicines and vaccine production status.</p> <p>Egypt and Pakistan make direct-acting antivirals available at affordable prices, using the flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to prohibit and revoke patents and to promote local production of patented medicines at lower prices.</p> <p>COVID-19 has affected pharmaceutical production enormously; China is one of the largest producers globally of active pharmaceutical ingredients, and import of raw materials was restricted with the start of the pandemic.</p>

Annex 2. Regional strategy to improve access to medicines and vaccine in the Eastern Mediterranean, 2020–2030: objectives, actions and expected outcomes

Strategic objectives	Actions by Member States	Actions by WHO and development partners	Expected outcomes (deliverables)
Strategic objective 1: Formulate, update, implement and monitor comprehensive national policies for medicines and vaccines, while ensuring all stakeholders' commitment to implementation	<p>Immediate actions</p> <p>1.1.1. Develop and implement a comprehensive national medicines and vaccines policy, with provisions on regulatory procedures and supply chain management including in cases of emergency, within the framework of the health system and national health policy.</p> <p>1.1.2. Review and update the national essential medicines list through a multisectoral participatory process and link with standard treatment guidelines, as a basis for procurement at different levels of the health system and for reimbursement.</p> <p>1.1.3. Maintain and ensure availability of and access to a priority list of medicines and health products as a basic human right, including during emergency situations (for example, medicines against COVID-19), and ensure that medicines and health products for priority health conditions are not abruptly halted.</p> <p>1.1.4. Establish a national immunization technical advisory group (NITAG), including independent national experts and meeting WHO guidelines; strengthen NITAG capacities in independent evidence-based decision-making, by providing administrative, logistical and financial support.</p> <p>1.1.5. Develop/update national immunization policy, including vaccination schedule, based on available evidence on vaccines and local disease epidemiology with guidance from the NITAG.</p> <p>1.1.6. Provide necessary incentives for the production, registration, procurement and distribution of essential medicines and vaccines (for example, fast-track registration, tax exemption, financing mechanisms).</p> <p>1.1.7. Establish a national technical committee to follow up implementation of the identified priority actions and to monitor progress in access to medicines and vaccines.</p> <p>Medium-term actions</p> <p>1.1.8. Establish and adopt a national good governance for medicines programme by formulating and implementing appropriate policies and procedures that ensure the effective, efficient and ethical management of pharmaceutical systems in a manner that is transparent and accountable, follows the rule of law and minimizes corruption.</p>	<p>1.2.1. Advocate for and provide technical support to the development, adoption and implementation of comprehensive national medicines and vaccines policies and essential medicines lists, and associated implementation plans including plans for continuous monitoring.</p> <p>1.2.2. Support evidence-based selection of medicines and health products, and raise awareness on the value of health technology assessment among policy-makers and provide guidance on best practices, by coordinating and facilitating collaboration between established organizations, networks and Member States.</p> <p>1.2.3. Support the implementation of multisectoral national action plans and health system strengthening to respond to emergency situations, including COVID-19, while ensuring access to other priority medicines and vaccines.</p> <p>1.2.4. Support capacity-building in the essential medicines concept, evidence-based selection and priority-setting, using various tools including health technology assessment.</p> <p>1.2.5. Provide technical support to establish/strengthen NITAGs and to develop/update national immunization policies, based on WHO guidelines.</p> <p>1.2.6. Facilitate and support capacity-building activities for NITAG members and chairs at national, regional and global levels including training programmes, twinning and participation in global and regional events; facilitate access of NITAG members to latest evidence and global recommendations on vaccines and new technologies.</p> <p>1.2.7. Advocate for establishing national good governance for medicines programmes to improve the transparency, accountability, quality and integrity of the pharmaceutical sector.</p> <p>1.2.8. Identify a core set of indicators to measure access to medicines and vaccines in consultation with Member States and relevant</p>	<p>1.3.1. National medicines and vaccines policies developed, monitored, impact-evaluated and regularly updated, and aligned with national health development policies and intersectoral plans.</p> <p>1.3.2. Strengthened regulatory procedures and supply chain management, including provisions related to emergency, pandemic and crisis situations.</p> <p>1.3.3. Access to essential medicines recognized as a human right, and the concept of essential medicines integrated into national health programmes and reinforced using an evidence-based approach.</p> <p>1.3.4. NITAGs established and functional in all Member States.</p> <p>1.3.5. All people in the Region benefiting from new innovations in vaccines and technologies, during childhood and throughout the life course.</p> <p>1.3.6. Information exchange between Member States on national medicines policies and other issues related to essential medicines.</p> <p>1.3.7. National essential medicines lists formulated, evaluated and revised through a participatory process involving stakeholders at different levels of the health system.</p> <p>1.3.8. National essential medicines lists used as a basis for procurement, prescribing, monitoring of access, and reimbursement by health financing mechanism (such as insurance scheme) at different levels of the health system.</p> <p>1.3.9. Selection, adoption and use of medicines and other health technologies are based on health priorities and undergo rigorous assessment according to the best available scientific evidence, taking into account social, intercultural, equity, gender and ethical implications as well as the context and sustainability of health systems.</p> <p>1.3.10. Increased access to essential medicines and health products for priority health conditions, including during emergency and pandemic situations.</p>

Strategic objectives	Actions by Member States	Actions by WHO and development partners	Expected outcomes (deliverables)
	<p>1.1.9. Establish a sustainable and effective national health technology assessment process to provide the basis for decision-making on the use, reimbursement and/or pricing of technologies, to enhance access and ensure value for money.</p> <p>1.1.10. Institute mechanisms for continuous measurement of access to medicines and vaccines, by identifying a core set of indicators to become part of routine data collection and analysis.</p> <p>1.1.11. Facilitate information exchange across national and international stakeholders and between countries on issues related to access to medicines and vaccines.</p>	<p>partners, and advocate for their inclusion in national routine data collection systems.</p>	<p>1.3.11. Strengthened capacity in health technology assessment and health technology management for evidence-based selection, priority-setting and effective management, including in collaboration with relevant partners.</p> <p>1.3.12. Ethical practices promoted and anti-corruption measures identified and implemented in the pharmaceutical sector</p>
<p>Strategic objective 2: Secure adequate and sustainable funding, and effective financing mechanisms with necessary flexibilities, to ensure regular supply of essential medicines and vaccines, with emphasis on priority diseases and vulnerable populations</p>	<p>Immediate actions</p> <p>2.1.1. Secure sufficient public funding for essential medicines and vaccines through improved financial management, especially for the public sector and primary health care, based on properly quantified health care needs.</p> <p>2.1.2. Ensure that essential medicines are covered by financial protection arrangements and create mechanisms for social safety nets.</p> <p>2.1.3. Include pharmaceutical financing policy in the national health and medicines policy and national health financing strategy.</p> <p>2.1.4. Review and evaluate the impact of current national health and medicines financing policies on access to essential medicines and vaccines.</p> <p>2.1.5 Establish a collaboration mechanism between ministries of health and finance to promote increased public funding for essential medicines and vaccines, including better public financial management rules.</p> <p>Medium-term actions</p> <p>2.1.6. Enhance and maintain a coordinated information system on sources of medicines financing and expenditures, as part of national health accounts or other national health financing information systems.</p> <p>2.1.7. Undertake regular financial and economic analysis of medicines expenditures, using cost-effectiveness analysis and other analytical tools for economic evaluation, especially in the public sector.</p> <p>2.1.8. Employ external funding for medicines for priority diseases with high public health impact when national financing is inadequate.</p>	<p>2.2.1. Undertake operational research to document the practice and implications of out-of-pocket payments for medicines; and promote prepayment arrangements to cover the cost of medicines, as part of broader health financing strategies.</p> <p>2.2.2. Support countries to establish or maintain a coordinated information system on sources of medicines financing and expenditures as part of national health accounts.</p> <p>2.2.3. Identify and disseminate policies and practices of Member States in equitable medicines financing and efficient and effective financial management.</p> <p>2.2.4. Develop methods and analytical tools to assess and monitor current medicines financing policies and practices of Member States.</p> <p>2.2.5. Provide support for the analysis of medicines financing and expenditures in order to improve cost-effectiveness, especially in the public sector.</p> <p>2.2.6. Support capacity-building in financial and pharmaco-economic analysis, including budget allocation for pharmaceuticals, and strengthen planning and management of human and financial resources involving both the ministries of health and finance.</p>	<p>2.3.1. Equitable and sustainable national medicines and vaccines financing strategies developed, as standalone strategies or part of the national financing strategy, to enhance access and ensure financial protection for all, including poor and vulnerable populations.</p> <p>2.3.2. Increased public funding for essential medicines and promotion of cost containment mechanisms.</p> <p>2.3.3. Sustainable methods of equitable financing of medicines and vaccines instituted as part of national financial protection arrangements.</p> <p>2.3.4. Improved financial planning skills in ministries of health, and increased awareness of medicines and vaccines financing in ministries of finance.</p> <p>2.3.5. Increased collaboration between ministries of health and finance in financial planning, and improved analysis of medicines and vaccines financing.</p> <p>2.3.6. Information systems on sources of medicines and vaccines financing and expenditures established or maintained.</p> <p>2.3.7. Financial and economic analysis of medicines expenditures conducted to identify areas for potential efficiency gains.</p> <p>2.3.8. Effective public subsidy mechanisms established to cover poor and vulnerable populations.</p> <p>2.3.9. Human resources development enhanced to improve financial analysis of medicines financing.</p>

Strategic objectives	Actions by Member States	Actions by WHO and development partners	Expected outcomes (deliverables)
Strategic objective 3: Ensure the availability of medicines and vaccines at fair and affordable prices in both the public and private sectors	<p>2.1.9. Investigate innovative funding options to expand coverage and reach poor and vulnerable populations.</p> <p>Immediate actions</p> <p>3.1.1. Establish and promote mechanisms that improve collaboration and information exchange on the price of medicines and vaccines with other countries of the Region.</p> <p>3.1.2. Share vaccine procurement information with other countries through WHO's Market Information for Access (MI4A) initiative and annual Joint Reporting Form; use MI4A information and analysis to benefit from best prices and global availability of vaccines.</p> <p>3.1.3. Conduct periodic surveys of medicine prices and availability; establish a routine monitoring system for medicine prices and availability; and investigate the underlying determinants of any issues encountered.</p> <p>3.1.4. Improve transparency in pharmaceutical and medicine pricing by disclosing the prices in the public and private sectors.</p> <p>3.1.5. Encourage collaboration among stakeholders involved in medicines pricing and reimbursement schemes.</p> <p>Medium-term actions</p> <p>3.1.6. Formulate and update pricing policies, including pricing informed by health technology assessment; promote the use of quality-assured generics and biosimilar medicines, tax exemptions or tax reductions, regressive mark-ups and reference pricing.</p>	<p>3.2.1. Identify and disseminate existing pricing policies, practices and feasible pricing options.</p> <p>3.2.2. Support efforts towards transparency in pharmaceutical pricing and monitor the impact of transparency on the affordability and availability of medicines and vaccines.</p> <p>3.2.3. Support the development of local price monitoring systems for selected essential medicines and information exchange on medicine prices between countries.</p> <p>3.2.4. Encourage Member States to participate in regional and global price monitoring systems and provide Member States with pricing information.</p> <p>3.2.5. Support countries to implement and improve policies that promote the use of quality-assured generic medicines.</p>	<p>3.3.1. Information exchange on medicine pricing policies, net prices and price components of medicines and vaccines between countries of the Region.</p> <p>3.3.2. Access to affordable vaccines and technologies improved in Member States.</p> <p>3.3.3. Best practices for pharmaceutical pricing policies disseminated.</p> <p>3.3.4. Generic medicines policies implemented to facilitate stronger competition and reduce prices.</p> <p>3.3.5. Reductions in taxes, duties and fees on essential medicines.</p> <p>3.3.6. Provision of comparative price information to health providers and consumers.</p> <p>3.3.7. Increased availability and affordability of essential medicines in the public and private sectors.</p>
Strategic objective 4: Establish efficient supply systems to ensure the flow of quality essential medicines and vaccines on a regular basis and in sufficient quantities to all levels of the distribution chain	<p>Immediate actions</p> <p>4.1.1. Develop comprehensive mechanisms to ensure effective procurement systems for medicines and vaccines.</p> <p>4.1.2. Establish a regional pooled procurement/joint purchasing mechanism for pharmaceuticals and vaccines.</p> <p>4.1.3. Procure medicines and vaccines for the public sector based on good procurement practices and the national essential medicines list.</p> <p>4.1.4. Develop and update national guidelines on good distribution practice and good storage practice for warehouses and pharmacies.</p> <p>4.1.5. Create a mechanism to communicate information to professional societies, health care providers and the public notifying of anticipated shortages and the substitutes that should be used.</p>	<p>4.2.1. Support countries to develop procurement policies/strategies for running public sector pharmaceutical supply systems to ensure availability of essential medicines and vaccines at all levels of the distribution chain.</p> <p>4.2.2. Support countries to improve coordination in medicine procurement by different programmes.</p> <p>4.2.3. Continue to collaborate with UNICEF Supply Division to facilitate pooled vaccine procurement.</p> <p>4.2.4. Advocate for development of regional policy and operational plans for pooled procurement/joint purchase of medicines and vaccines.</p> <p>4.2.5. Provide technical support and training in supply chain management to Member States.</p> <p>4.2.6. Monitor prices of selected essential medicines and facilitate information exchange</p>	<p>4.3.1. Supply systems assessed, and procurement policies/strategies developed and implemented.</p> <p>4.3.2. Adoption and implementation of good procurement practices in countries.</p> <p>4.3.3. Pooled vaccine procurement system established in the Region.</p> <p>4.3.4. Collective price negotiations for procurement of essential medicines and vaccines promoted.</p> <p>4.3.5. Capacity built in procurement management of medicines and vaccines.</p> <p>4.3.6. Information exchange on medicine and vaccine prices and procurement sources among countries.</p> <p>4.3.7. Good and ethical pharmaceutical practices in public and private sectors identified and promoted.</p>

Strategic objectives	Actions by Member States	Actions by WHO and development partners	Expected outcomes (deliverables)
	4.1.6. In case of emergency or pandemic situations, establish an effective procurement system that includes emergency standard operating procedures for logistics/fast-track procurement and distribution of essential medicines and vaccines, aligned with clinical management guidelines, to ensure timely and equitable access to life-saving interventions.	<p>on medicine and vaccine prices and procurement sources.</p> <p>4.2.7. Promote the use of WHO prequalified medicines and vaccines.</p> <p>4.2.8. Support operational research to document and evaluate pharmaceutical supply systems and procurement practices in the public and private sectors.</p> <p>4.2.9. Support Member States to develop transparent and efficient procedures for all emergency procurement actions.</p>	<p>4.3.8. Supply management systems strengthened and human resources capacity built in pharmaceutical supply management.</p> <p>4.3.9. Mechanism created to communicate information to professional societies, health care providers and the public notifying of anticipated shortages and the substitutes that should be used.</p> <p>4.3.10. Development of procurement procedures, including emergency standard operating procedures for logistics/fast-track procurement, to ensure proper procurement process for medicines and vaccines including in emergency and pandemic situations.</p>
Strategic objective 5: Strengthen national regulatory authorities to ensure the quality, safety and efficacy of medicines and vaccines	<p>Immediate actions</p> <p>5.1.1. Provide needed means, infrastructure and funds to establish an independent, comprehensive and autonomous national regulatory body.</p> <p>5.1.2. Conduct national regulatory authority (NRA) self-assessment and NRA benchmarking exercise, and formulate an institutional development plan to strengthen regulatory capacities and enforcement of legislation.</p> <p>5.1.3. Explore approaches to utilize the concept of reliance and improve collaborative decision-making to increase timely access to safe and effective medicines and vaccines.</p> <p>5.1.4. Establish fast-track mechanisms to ensure timely registration and quicker access to medicines and vaccines, especially in emergency situations.</p> <p>5.1.5. Support capacity-building of regulatory activities including pharmacovigilance, regulation of bioterapeutics, good manufacturing practice, and combating substandard and falsified medical products.</p> <p>5.1.6. Publish a list of medicine shortages, and encourage local manufacturers to produce and wholesalers to import them by providing a fast-track registration scheme.</p> <p>Medium-term actions</p> <p>5.1.7. Establish tracing systems, such as barcodes to identify the manufacturers and batches produced.</p> <p>5.1.8. Enforce regulations to ensure antimicrobials are dispensed only based on prescription.</p>	<p>5.2.1. Support countries to establish and maintain effective medical product regulation and quality assurance systems.</p> <p>5.2.2. Advocate for establishing a regional network or centre of excellence to foster collaboration, exchange information, build capacity, initiate convergence, share work and harmonize regulatory activities.</p> <p>5.2.3. Promote the concept of reliance, where appropriate, and facilitate collaborative decision-making at the regional level.</p> <p>5.2.4. Support countries to implement NRA self-assessment and conduct NRA benchmarking exercise to identify gaps, formulate institutional development plans, and build capacity to reach minimum maturity level 3 (for consideration as WHO Listed Authorities).¹</p> <p>5.2.5. Facilitate access of NRAs and pharmaceutical control authorities to reliable information management systems and mechanisms for exchange of independent information on the quality, safety and efficacy of marketed products, as well as access to safety information from clinical trials and other related activities.</p> <p>5.2.6. Support Member States to strengthen the capacity of NRAs to assess and monitor the quality, safety and efficacy of medicines and</p>	<p>5.3.1. Effective implementation and monitoring of medicine regulations.</p> <p>5.3.2. NRA regional network/centre of excellence initiative developed and stakeholders engaged to ensure the added value and strength of the regional network/centre of excellence is promoted and understood.</p> <p>5.3.3. Enhanced regulatory coordination, collaboration and harmonization in the Region; and information exchange between countries on medicine regulatory affairs promoted, particularly for inspection, medicine registration, product evaluation and pricing.</p> <p>5.3.4. NRA self-assessments conducted, facilitated by WHO.</p> <p>5.3.5. Good regulatory and reliance practices in medicine regulation, and quality assurance systems implemented.</p> <p>5.3.6. Post-marketing surveillance of medicine and vaccine safety maintained and strengthened.</p> <p>5.3.7. Use of substandard and falsified medical products reduced, and rapid alert mechanism for falsified medical products promoted and implemented.</p> <p>5.3.8. Development of comprehensive strategies to combat substandard and falsified medical products, involving relevant stakeholders including private manufacturers.</p> <p>5.3.9. Increased number of prequalified pharmaceutical products manufactured in the</p>

¹ WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medicines and vaccines (revision VI, version 1, 2018), https://www.who.int/medicines/regulation/benchmarking_tool_version_vi.

Strategic objectives	Actions by Member States	Actions by WHO and development partners	Expected outcomes (deliverables)
	<p>5.1.9. Engage NRAs in national preparedness planning processes for public health emergencies.</p> <p>5.1.10. Express political acceptance of and commitment to regulatory harmonization and collaboration among NRAs in the Region for the convergence of regulatory requirements and sharing results of inspections and product evaluations.</p>	<p>vaccines and to detect substandard and falsified medical products.</p> <p>5.2.7. Assist countries to document best practices in improving access to medicines and establishing regulatory mechanisms for essential medicines susceptible to shortage.</p> <p>5.2.8. Support countries to strengthen local production of quality-assured essential medicines and vaccines at affordable prices.</p> <p>5.2.9. Provide technical support for national quality control laboratories in the Region to become WHO-prequalified.</p>	<p>Region, and increased number of prequalified quality control laboratories.</p> <p>5.3.10. Improved medicine and vaccine manufacturing, distribution and inspection practices.</p> <p>5.3.11. Good manufacturing practices strengthened, and improved collaboration between NRAs and manufacturers on compliance with good manufacturing practices.</p> <p>5.3.12. Strengthened capacities and skills of NRAs in the areas of good manufacturing practice, pharmacovigilance, marketing surveillance, inspection and product evaluation.</p>
<p>Strategic objective 6: Ensure appropriate use of medicines by health professionals and consumers</p>	<p>Immediate actions</p> <p>6.1.1. Develop and implement a comprehensive strategy on rational use of medicines, including interventions to contain antimicrobial resistance.</p> <p>6.1.2. Develop education programmes and other effective mechanisms to promote rational use of medicines by all health professionals.</p> <p>6.1.3. Develop and implement standard treatment guidelines and formularies linked to the national essential medicines list.</p> <p>6.1.4. Establish pharmacy and therapeutics committees in hospitals, including clear tasks and functions.</p> <p>6.1.5. Evaluate and monitor medicine use practices and interventions in health care facilities.</p> <p>6.1.6. Develop and implement regulations on the ethical promotion of pharmaceuticals.</p> <p>6.1.7. Conduct public awareness campaigns and consumer education programmes to raise awareness on rational use of medicines.</p> <p>Medium-term actions</p> <p>6.1.8. Introduce the concepts of essential medicines, access to medicines and vaccines, national medicines policy, and rational use of medicines into the university curricula of medical students and continuing education programmes for health care providers.</p> <p>6.1.9. Establish effective systems to provide independent and unbiased drug information to improve use of medicines by consumers.</p>	<p>6.2.1. Support Member States to develop, implement and evaluate comprehensive strategies to promote rational use of medicines by health professionals and consumers.</p> <p>6.2.2. Support countries to develop and implement standard treatment guidelines and formularies linked to national essential medicines lists.</p> <p>6.2.3. Advocate and support countries to conduct evaluation of medicine use interventions.</p> <p>6.2.4. Document and share experiences/success stories with countries on effective interventions for the rational use of medicines.</p> <p>6.2.5. Advocate for and support countries to establish pharmacy and therapeutics committees in hospitals, including clear tasks and functions.</p> <p>6.2.6. Provide technical support to countries on controlling pharmaceutical promotion, and advocate the use of ethical criteria for pharmaceutical promotion.</p> <p>6.2.7. Develop model curricula on national medicines policies, access to medicines and vaccines, and rational use of medicines for introduction into the university curricula of medical students.</p> <p>6.2.8. Develop advocacy and training materials on the concepts of essential medicines and rational use of medicines targeted towards stakeholders and health care providers, as part of continuing education programmes, in the public and private sectors.</p>	<p>6.3.1. Rational use of medicines by health professionals and consumers advocated.</p> <p>6.3.2. Development of national standard treatment guidelines linked to essential medicines lists, and implementation of formulary processes.</p> <p>6.3.3. Independent and reliable information on medicine use identified, disseminated and promoted.</p> <p>6.3.4. Implementation of ethical criteria for pharmaceutical promotion, monitoring of pharmaceutical promotion, and restriction of unacceptable promotion through regulation and/or voluntary codes of conduct.</p> <p>6.3.5. Pharmacy and therapeutics committees established at institutional and national level, and operating effectively.</p> <p>6.3.6. Strengthened networking and information exchange, and successful strategies for rational use of medicines identified and promoted.</p> <p>6.3.7. Increased awareness of and guidance on cost-effective and rational use of medicines, with a view to improved medicine use by health professionals and consumers.</p> <p>6.3.8. Increased support for problem-based and skill-based in-service training programmes.</p> <p>6.3.9. Increased public education and consumer empowerment on rational use of medicines.</p> <p>6.3.10. Development and implementation of appropriate strategies to contain antimicrobial resistance.</p> <p>6.3.11. Development and implementation of a package of interventions for providers and consumers on the rational use of medicines.</p>

Strategic objectives	Actions by Member States	Actions by WHO and development partners	Expected outcomes (deliverables)
Strategic objective 7: Promote research and development and the local production of quality medicines and vaccines that meet public health needs	<p>Immediate actions</p> <p>7.1.1. Implement intellectual property policies and use flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in cases of national emergency, pandemic or other circumstances of extreme urgency, as determined by each Member State, in a timely and appropriate manner.</p> <p>7.1.2. Review and monitor through a multisectoral approach all national policies, legislation, the TRIPS Agreement and other multilateral, regional and bilateral agreements that affect pharmaceutical manufacturing, distribution, importation and exportation to increase the supply of affordable quality medicines.</p> <p>7.1.3. Develop a national strategy to promote local production of essential medicines, ensuring policy coherence and promoting an enabling business environment to provide incentives for local production and mechanisms for scaling up production in emergency and pandemic situations.</p> <p>7.1.4. Scale up production of safe, effective, quality, affordable medicines and vaccines for the COVID-19 response, using existing mechanisms for voluntary pooling and licensing of patents to facilitate timely and equitable access consistent with the provisions of relevant international treaties including the TRIPS Agreement and its flexibilities as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health.</p> <p>Medium-term actions</p> <p>7.1.5. Adopt a mechanism to enhance collaboration and information exchange with other countries in the Region to improve access to essential medicines as related to trade globalization, the TRIPS Agreement and other agreements relevant to intellectual property.</p> <p>7.1.6. Amend national intellectual property laws taking into account the public health perspective.</p>	<p>6.2.9. Develop materials for educating and empowering consumers in the area of rational use of medicines.</p> <p>7.2.1. Provide technical assistance to Member States on the use of flexibilities and safeguards in their national legislation, in accordance with the Doha Declaration.</p> <p>7.2.2. Support countries that have insufficient or no manufacturing capacity in the pharmaceutical sector to make effective use of compulsory licensing under the TRIPS Agreement, in cases of national emergency, pandemic or other circumstances of extreme urgency, as determined by the country.</p> <p>7.2.3. Monitor and provide independent data and analysis on the pharmaceutical and public health implications of relevant international trade agreements, including World Trade Organization (WTO) agreements, to assist countries in the effective assessment and development of pharmaceutical and health policies and regulatory measures that maximize the positive and mitigate the negative impacts of such agreements.</p> <p>7.2.4. Support countries to assess national policies on health, trade and intellectual property laws, and to amend legislation to include the public health safeguards of the TRIPS Agreement.</p> <p>7.2.5. Support capacity-building in trade globalization and access to medicines for health and trade policy-makers.</p> <p>7.2.6. Support collaboration among Member States and facilitate exchange of country experiences in dealing with TRIPS and other agreements, especially in protecting public health.</p> <p>7.2.7. Support capacity-building in research and development and clinical trials for medicines and vaccines that meet public health needs in countries.</p>	<p>combining educational, managerial, regulatory, financial and systems interventions.</p> <p>6.3.12. Increased human resources capacity in the pharmaceutical sector.</p> <p>6.3.13. Inclusion of essential medicines, rational use of medicines and national medicines policy in undergraduate curricula of health care professionals and continuing education programmes.</p> <p>7.3.1. Information exchange on the impact of trade agreements on access to essential medicines.</p> <p>7.3.2. Exchange of country experiences in dealing with the TRIPS Agreement and other agreements, especially with regard to securing public health.</p> <p>7.3.3. Strengthened national capacity to deal with trade-related matters that influence access to essential medicines and vaccines.</p> <p>7.3.4. Collaboration between health and other sectors (such as trade, finance and justice) and stakeholders (such as nongovernmental organizations and universities) to ensure that national health objectives are taken into account when there are any changes to WTO agreements, national, regional or multilateral legislation related to regulations.</p> <p>7.3.5. Technical support provided to make use of the provisions of the TRIPS Agreement and other WTO instruments.</p> <p>7.3.6. Access to medicines and vaccines promoted within international trade agreements.</p> <p>7.3.7. Research and development of pharmaceutical products is aligned with global health needs.</p> <p>7.3.8. Promotion of technology transfer and production of medicines and vaccines in the Region.</p> <p>7.3.9. Local pharmaceutical production matched to public health needs.</p>

Strategic objectives	Actions by Member States	Actions by WHO and development partners	Expected outcomes (deliverables)
	7.1.7. Strengthen research and development for medicines and vaccines that meet public health needs.	<p>7.2.8. Support Member States to strengthen local production and technology transfer, especially for biologicals and vaccines, through policy and strategy setting, conducting situation analyses for sustainable quality local production, building capacity of manufacturers, regulators and other stakeholders, and forging strategic partnerships and collaborations.</p> <p>7.2.9. Indicate and provide choices that comply with the provisions of relevant international treaties, including TRIPS, and flexibilities to be used to scale up development, manufacturing and distribution capacities needed for transparent, equitable and timely access to medicines and vaccines for COVID-19 response, taking into account existing mechanisms, tools and initiatives including the Access to COVID-19 Tools (ACT) Accelerator.</p>	
<p>Strategic objective 8: Establish a strong partnership framework with all relevant sectors and stakeholders, leveraging the comparative advantages of each, to promote the regional and national agenda of improving access to medicines and vaccines for all</p>	<p>Immediate actions</p> <p>8.1.1. Organize policy dialogue on access to medicines and vaccines, as part of the national and regional health security agenda, bringing together all stakeholders including industry.</p> <p>8.1.2. Identify roles and responsibilities of various stakeholders, based on the comparative advantages of each, and ensure their commitment to the realization of the strategic objectives of the strategy at both regional and national levels.</p>	<p>8.2.1. Leverage the convening power of WHO to bring together all partners and stakeholders, at regional and national levels, to facilitate dialogue and consensus on roles and responsibilities.</p> <p>8.2.2. Facilitate agreement between partners and stakeholders, at regional and national levels, in relation to various stages of medicines and vaccines life-cycle and value chain.</p>	<p>8.3.1. Strong partnership frameworks developed at regional and national levels.</p> <p>8.3.2. Regional observatory on medicine and vaccine prices established.</p>