

**OHCHR analytical study on key challenges in ensuring access to medicines, vaccines and other health products (HRC resolution 50/13)**

***November 2023***

## Access to vaccines: Lessons learned, key bottlenecks and way forward[[1]](#footnote-1)

The past two decades have seen important progress in access to vaccines of public health importance, with new vaccines developed and distributed globally, saving millions of lives and averting disease. Nevertheless, an extensive assessment of global vaccine market dynamics still shows significant challenges.

The many new vaccines developed against key diseases, such as meningococcal meningitis A, hepatitis E and malaria, translate into millions of lives saved. However, diseases associated with markets of little commercial value remain neglected and face suboptimal investment, few products in the development pipeline, extended timelines, and delays in availability.

There is a large and expanding manufacturing base, with more than 90 manufacturers supplying vaccines to World Health Organization (WHO) Member States (2021 data). However, supply remains highly dependent on fewer than 10 manufac­turers with broad portfolios, global reach and a diversity of deployable technology. Even more importantly, when looking at individual vaccines, often only two or three suppliers provide most of the supply. Trends are positive, with an increased contribution of manufacturers from additional countries, but more distributed manufacturing capabilities are needed. This concentration leads to market health issues and regional supply insecurity, particularly in the WHO African and Eastern Mediterranean regions, making access to vaccines heavily dependent on the policies and supply chains of other regions.

In addition, vaccine supply has historically been unable to rapidly respond to significant changes in demand, both owing to technological challenges and to a lack of market incentives. Vaccines are typically manufactured in prod­uct-specific facilities and product changeovers are cumbersome, limiting flexibility. At the same time, manufacturing know-how, intellectual property rights protection, non-linear production costs, uncertain demand and displacing competi­tion limit manufacturer incentives to scale up.

Coordinated procurement and financing mech­anisms, particularly for lower-income settings, have reduced gaps in access, enhancing earlier availability in lower-income countries and more favourable vaccine pricing. Yet, equitable and efficient distribution of vaccines continues to suffer, as indicated by vaccines such as for pneu­mococcus and human papillomavirus.

On the demand side, important efforts have been made to support country planning, forecasting and budgeting: predictable country demand is key to guiding investments. However, more investment and focused effort are needed to facil­itate universal vaccination with all recommended products and to enhance the diversification of the vaccines procured, increasing the reach of the vaccination programme and counter the growing threat of vaccine hesitancy. It is important that the contribution of vaccines to the well-being and prosperity of citizens is fully recognized and that clear vaccine programme priorities and objec­tives are set, proper planning is executed and budgetary appropriations are made accordingly.

The COVID-19 pandemic has given unprece­dented visibility to vaccine market dynamics and has shown that some of these challenges can be overcome.

The vaccine community made new vaccines available in less than one year while using innovative technology platforms that enabled faster scalability. This achievement resulted from unprecedented public investment, early and parallel at-risk investment in clinical devel­opment and manufacturing capacity and the streamlining of regulatory processes. Those factors, combined with the size of the population targeted by COVID-19 vaccines, led to a three-fold increase in vaccine doses procured globally within 12 months.

This incredible achievement in the face of a public health emergency of international concern made stark the long-standing need to recon­sider the value of vaccines as a fundamental and cost-effective public good rather than a commodity. We must acknowledge both that vaccines are under-invested and that free-market dynamics do not optimize for social and health impact. Without strong public engagement, the strategic focus and investments of manufac­turers will remain limited relative to the need for an ambitious immunization agenda and will continue to concentrate on more profitable phar­maceutical interventions and on high-income market vaccines.

COVID-19 has also shown that large public invest­ment, streamlined processes, new technologies, pooled financing and procurement are not suffi­cient to achieve optimal public benefit. Efficient and equitable access to COVID-19 vaccines has been highly problematic as a result of dynamics repeatedly experienced in other vaccine markets. The lack of transparency along the value chain of vaccine manufacturing and distribution and the lack of government oversight made it hard for governments to plan and use vaccines most efficiently within national boundaries as well as across countries. Despite the impressive number of approximately 15 billion doses delivered glob­ally through various mechanisms as of October 2022, COVAX accounted for only 12% of this volume, indicating that serving all populations more equitably and ending future pandemics requires more than financing and procurement efforts. We need to enhance government over­sight of vaccine production and distribution and strike a much better balance between serving national interests and global public health objectives. The only means to achieve this is through high-level diplomacy between countries and pre-defined and binding rules for vaccine distribution at a time of scarcity. We also must work on a more favourable intellectual property landscape, proactive technology transfers and the building and retention of local technical and regulatory capacity. We should acknowledge that additional dedicated and permanent manufac­turing capacity is costly and should be valued not only as means to satisfy current vaccine demand but also as an insurance against future public health needs.

We have an opportunity to establish a new para­digm for vaccine development and access that builds on new practices and some of the lessons learned during the COVID-19 pandemic. This new paradigm could be incorporated as part of a new international accord on pandemic prevention, preparedness and response. In this new paradigm, stakeholders need to assume their shared but differentiated responsibilities; that is, governments need to commit to:

1. Establish early, evidence-informed strategic goals and leadership that serve the collective global health interest and to shoulder risks and invest aggressively in order to address the needs of today and prepare for future emergencies.
2. Strengthen market preparedness by investing in new vaccine technologies, regional research and development and manufacturing hubs, and by enabling regula­tory harmonization.
3. Ensure transparency and oversight along the vaccine value chain towards enhanced health impact, as well as, define principles and operational mechanisms for collabo­ration across countries in times of scarcity, including for intellectual property and the circulation of inputs and goods.

The industry to commit to:

1. Ensure that activities are aligned with WHO’s guidance: research and development efforts focused on the WHO list of priority pathogens

and target product profiles, more clinical trials performed in low-income countries, and targeted to inform global policy needs and expedited data submissions for regula­tory approvals and prequalification.

2. Establish provisions for technology transfer and ensure transparency along the vaccine value chain.

3. Commit to specific measures allowing for equity-driven allocation of products.

And international organizations and partners to commit to:

1. Prioritize the achievement of global public health priorities as per the Immunization Agenda 2030 as an umbrella for individual organizational strategies, priorities and interests.
2. Support country-driven initiatives and proj­ects consistently with organizations’ missions and avoid the creation of duplicate efforts.
3. Continue to call for technology transfer and for the application of resolutions on market transparency for health products.

In the next pandemic, this paradigm would serve both equity and national interests by reducing disease everywhere through a faster, more coordinated and more equitable global response. Between pandemics, this paradigm would enable bolder, coordinated leadership to improve access to vaccines for all.

## Access to medicines and health products: Key challenges **[[2]](#footnote-2)**

The availability, accessibility, acceptability, and affordability of health products of assured quality need to be addressed in order to achieve the Sustainable Development Goals, in particular target 3.8.[[3]](#footnote-3) Every disease management strategy requires access to health products for prevention, diagnosis, treatment, palliative care and rehabilitation. Ensuring access to health products depends on the components of a well-functioning health system[[4]](#footnote-4), in particular financing, governance, human resources and health information. Access is a multidimensional challenge that requires comprehensive national policies, strategies and regulatory frameworks to cover the entire product life cycle, from research and development to quality assurance, supply chain management and use.

Many people worldwide do not have adequate and regular access to health products. Many medical devices in resource-poor settings are broken, unused or unfit for purpose. Access depends on having appropriate products available at affordable prices. This is a particular challenge in small island States and for small markets, such as children’s medicines. The introduction of new medicines and other health products and the rise of noncommunicable diseases are putting increasing pressure on health care systems around the world and on individuals who pay out-of-pocket in the case of lack of government financing. Lack of access can affect patient outcomes if patients go undiagnosed or untreated or receive suboptimal treatment and can contribute to the rise in antimicrobial resistance. Challenges for improving access occur throughout the system, ranging from inadequate investment in research and development, lack of effective policies, weak procurement and supply chain management, and inappropriate prescribing and irrational use of health products.

Inadequate financing of health products, high prices of new health products and ineffective policy interventions and processes to manage expenditure, such as the ineffective use of policies for generic and biosimilar medicines, contribute to the challenges facing the health system in achieving universal health care. Evidence indicates that up to one fifth of health spending could be channelled towards better use by avoiding waste that occurs when health products are priced higher than is necessary, when less expensive but equally effective alternatives are not used and when purchased products are not used at all.

Good governance is recognized as a major hurdle on the road to achieving universal health coverage. Weak governance complicates access to health products by fuelling inefficiencies, distorting competition and leaving the system vulnerable to undue influence, corruption, waste, fraud and abuse. There is a pressing need to improve access to timely, robust and relevant information concerning health products. Unbiased information that is free of any conflict of interest is vital for the sound selection, incorporation, prescription and use of health products. Transparency of this information is central to accountability, strengthens confidence in public institutions and improves the efficiency of the system.

Health workforce shortages concern pharmacists and biomedical engineers, both essential to the development, regulation, production, procurement, distribution and appropriate use and maintenance of health products. Many of the interventions needed to improve the workforce are cross-cutting, such as mainstreaming relevant competencies in the pre-service education curricula of health personnel, scaling up the training of pharmacists, pharmacy assistants and biomedical engineers, and ensuring dedicated training for personnel in administrative and management positions within the supply chain. Some of the actions needed to strengthen the health workforce responsible for health products may be similar to – or implemented as part of – broader health workforce policies, including improving public sector pay and incentives, establishing mechanisms for access to education and training in rural areas and reforming education strategies to reflect current and emerging health system needs.

Information is essential for decision-making, monitoring policy implementation and establishing accountability. To make accurate and useful decisions, timely and accurate data and information are needed in such categories as national expenditures on health products; the procurement of health products, supply chain and distribution; pharmaco-vigilance and post-marketing surveillance; health insurance coverage; prescription prices of health products; and the availability of medicines and other health products in health facilities. Monitoring access to health products is a complex endeavour that requires gathering information from multiple sources and ensuring the interoperability of various data collection systems.

National regulatory authorities in countries are responsible for the quality, safety and efficacy of health products. Unfortunately, the capacity of many low- and middle-income countries to assess and approve health products remains limited. Key challenges to strengthen regulatory capacity include inadequate resources, overburdened staff and incoherent policy frameworks. Differences between national regulatory systems create challenges for researchers and manufacturers, who must navigate multiple regulatory systems to register the same health product in different countries. The underreporting of adverse drug reactions and adverse events highlights the need for improved approaches to post-marketing surveillance. In addition, the presence of substandard and falsified products in all markets is hamper efforts to ensure the quality, safety and efficacy of health products. A specific challenge related to enabling rapid access to novel health products has been highlighted by COVID-19 pandemic.

Neglected diseases and other major global health problems cannot be addressed with the health products that are currently available in markets, including for emerging infectious disease pathogens, and new antibiotic therapies. Some of the key challenges facing R&D include setting priorities for research and development needs, defining desired product profiles, incentivizing research and development for health products that have a potentially limited return on investment and coordinating the of different actors. Other challenges include the impact of trade agreements and intellectual property protection on public health and access to health products and the need to foster a better understanding of the linkage between public health and intellectual property policies and enhancing a mutually supportive implementation of those policies.

Poor selection of health products, inadequate financing and ineffective policy interventions and processes to manage expenditure, including out-of-pocket expenditure, contribute to a lack of access and unaffordable prices. There is an increasing need to ensure the sustainable availability of health products through careful management of affordable pricing for health systems and fair pricing for producers.

Inefficient procurement and supply chain management is another major challenge. The special skills required for the procurement of quality assured products are lacking in many countries. The supply chain requires a strong infrastructure and accurate data management systems. This can be particularly complex for temperature- or time-sensitive health products that require careful handling and efficient cold chain systems. Preventing, detecting and responding to shortages of health products is complex as well. In the case of infectious diseases, such shortages or stock-outs contribute to growing antimicrobial resistance and have an impact on health outcomes. Inefficient supply chain management can lead to high levels of wastage, with significant consequences in terms of access. Waste management is also an emerging public health problem, particularly for products such as antibiotics.

Particular challenges for medical devices include a lack of biomedical engineering capacity to advise on their suitability for use in resource-poor settings such as those with high temperature, fluctuating electricity or lack of clean water. Installation, maintenance services and user training are also often lacking, leading to unsafe handling practices with potentially harmful consequences, such as misdiagnosis due to improper use or calibration of equipment.

Estimates have shown that in low- and lower-middle income countries, less than 40% of primary‑care patients in the public sector and less than 30% of primary-care patients in the private sector are treated in accordance with standard treatment guidelines. Factors that contribute to inappropriate prescribing, dispensing and use include an inadequately trained workforce, incorrect diagnoses, the prohibitive costs or simple unavailability of medicines, and activities related to product marketing and promotion. Policy approaches and interventions have been identified to improve the use of health products but have generally not been implemented over the past decade. Increasing burdens on health resources, the rise of antimicrobial resistance to dangerously high levels and the rise in noncommunicable diseases require a renewed focus on appropriate prescribing dispensing and use.

1. This section is based on the [WHO Global Vaccine Market Report 2022](https://www.who.int/publications/i/item/9789240062726), developed under the [Market Information for Access Initiative (MI4A)](https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/mi4a/technical-advisory-group-mi4a), launched in 2018 to contribute to the achievement of Strategic Development Goal 3.8 (Universal Health Coverage target) by enhancing access to safe, effective, quality and affordable vaccines for all. [↑](#footnote-ref-1)
2. Based on the [Road map for access to medicines, vaccines and other health products, 2019-2023, Comprehensive support for access to medicines, vaccines and other health products](https://www.who.int/publications/i/item/9789241517034). [↑](#footnote-ref-2)
3. Achieve universal health coverage, including financial risk protection, access to quality essential health care services, and access to safe, effective, quality and affordable essential medicines and vaccines for all. [↑](#footnote-ref-3)
4. The six components of a well-functioning health system outlined in the WHO document “Key components of a well-functioning health system” include: Leadership and governance, health information systems, health financing, human resources, essential medical products and technologies, and service delivery. [↑](#footnote-ref-4)