

Policymakers' corner

COOPERATING TO OVERCOME ACCESS INEQUITIES FOR COVID-19 AND BEYOND

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The COVID-19 pandemic has highlighted how fragile the global health product value chain truly is to respond effectively to public health emergencies, making it necessary to invest in research and the development of new technologies, scale up production of them and enable their rapid dissemination. Investing in local production has shown promise towards alleviating market concentration, which is putting global health security at risk. Efficient regulation is needed to ensure quality, safety and efficacy of health products. Pricing policies and procurement strategies should align with principles of equitable access and affordability. Lessons learned from the COVID-19 pandemic must be applied and greater cooperation is required to strengthen health systems and improve interventions affecting all citizens.

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It has been more than two-and-a-half years since the World Health Organization (WHO) issued the highest-level alert for the COVID-19 from the International Health Regulations (IHR) – a public health emergency of international concern – and yet the world is still fighting this virus. Learning to live with COVID-19 involves using the tools available to protect ourselves and protect others.

Nevertheless, in countries with high vaccine coverage, even in the presence of highly transmissible variants, such as omicron, there is a dangerous narrative that the pandemic is over. Each country is facing a different situation with different challenges, but the fight against this virus is not over. The tools and the knowledge to end the pandemic as a global health emergency this year are available, so WHO is calling on all countries to remain vigilant, to continue to vaccinate, test, provide early care for patients, and apply public health and social measures to protect their populations.

At the same time, there is a concerning decrease in use of public health and social measures, and testing in many countries, coupled with very uneven vaccine coverage. These conditions have been “ideal” for new variants to emerge. Vaccines are among the most powerful inventions in human history, and the development and authorization of several COVID-19 vaccines in record time is a triumph from science that has helped to change the course of this pandemic. While vaccine coverage has improved, the reality of persistent inequity and uneven roll-out in vaccine access still is not fully addressed. Situations such as high-income countries having administered ten times more doses per inhabitant compared to low-income countries are simply unacceptable.

It has become clear during this pandemic how fragile the global health product value chain truly is. In 2019, WHO published *Roadmap for Access to Medicines, Vaccines and Health Product 2019–2023* outlining the interrelated nature of the health product value chain and the need for comprehensive support to enable access and affordability (WHO, 2019). Some key steps along the value chain where global and regional collaboration can help address this issue are intellectual property management, manufacturing and local production, regulatory reliance and harmonization, and pricing and procurement practices.

Intellectual property management

Intellectual property rights and the laws that govern them have traditionally been viewed by some as an incentive for the development of new health products. The debate about a Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver recently at WTO exposed the potential negative impact of intellectual property on access. An ongoing area of debate is how to enable such innovation while also mitigating barriers to technology transfer and facilitating affordable access. WHO

encourages countries to use all available tools, including the TRIPS flexibilities, where appropriate.

A cooperative mechanism launched by WHO in 2020, at the request of Costa Rica and supported by 43 countries, was the COVID-19 Technology Access Pool, known as C-TAP. The main objective of C-TAP is to promote voluntary mechanisms to share intellectual property through the Medicines Patent Pool (MPP), knowledge, and data (WHO, n.d.). The first technology transfer agreement involving C-TAP was with the Spanish National Research Institute for a worldwide, transparent, and non-exclusive voluntary licence for a COVID-19 test. Recently, the United States National Institutes of Health has also offered several technologies to C-TAP. Negotiations with other developers are ongoing, and C-TAP will host an open database of key COVID-19 products, including patent status and licensing information. The collaboration with the pharmaceutical industry was also critically important to grant access to novel and repurposed generic therapeutics in lower middle-income countries.

Manufacturing and local production

Production of medicines, vaccines and other health products is concentrated in a few countries, with new technologies being produced in even fewer countries. While this had been recognized as an issue prior to the COVID-19 pandemic, the inequitable access, mainly to vaccines during this pandemic, has catalysed enormous interest from WHO member States and regional bodies to invest in local production. By broadening manufacturing capacity not only of vaccines, but also of medicines, medical devices and health products, such as personal protective equipment, the global health supply chain can be better aligned with the goals of health security, equitable access and affordability, and the risk of having serious constraints on the global supply chain mitigated during lockout periods.

To that end, WHO and partners have established an mRNA Technology Transfer Hub in South Africa. The vision for the Hub is to improve health security in low- and middle-income countries through the sustainable, regional production of vaccines with facilities where manufacturers from low- and middle-income countries can receive training and technology transfer to produce mRNA vaccines. Thirteen “Spokes” in the six WHO regions will receive training on mRNA technologies in South Africa. This “Hub and Spoke” model is a promising way forward to enable the transfer of promising and essential technologies.

The partner in South Africa, Afrigen, already produced its own mRNA vaccine candidate in early 2022 and is beginning the clinical trial process for this product. However, this process would have been accelerated if the originator companies had been willing to share intellectual property and technology transfer with the Hub. Moving forward, the mRNA Technology Transfer Hub holds great potential, not just

for increasing access to vaccines against the Covid-19 disease, but also for other diseases, such as malaria, tuberculosis, and cancer.

Another factor is that manufacturing facilities for biologics other than vaccines are primarily in high-income countries, putting biotherapeutics out of reach for many countries. This is already a cause for inequity in access to many biological products. WHO (and the WHO Academy) has partnered with the Republic of Korea to set up a global biomanufacturing training hub to serve low- and middle-income countries that wish to produce not just vaccines, but other biologics, including insulin and monoclonal antibodies.

Local production is critical to making life-saving, quality assured health products available and affordable – not only now, but for the future. The diversification of production is key for countries to having a reliable supply of medicines, vaccines and other health products. This will not only make the world more resilient against future health emergencies, but it will also create jobs and economic opportunities. Collaboration on training, technology transfer, research and strengthening regulatory systems are key – engagement of regional bodies, such as the Association of Southeast Asian Nations (ASEAN) is essential.

Regulatory reliance and harmonization

At the same time, efficient regulation of medical products is needed now more than ever to face the current regulatory oversight challenges posed by the global pandemic and to ensure the quality, safety and efficacy of health products. Reliance and cooperation among regulators have been essential in facilitating emergency authorizations for COVID-19 health tools and rapid responses when suspected side effects have emerged (WHO, 2021d).

Countries embarking on local production, as outlined above, must strengthen their regulatory capacity to ensure the quality of products manufactured. WHO supports countries in providing such access through regulatory system strengthening, the prequalification programme and post-market surveillance. Through strengthening adherence to international norms and standards, regulatory capacity-building and cooperation, countries worldwide can regulate health products consistently and enable rapid access to quality-assured products.

Pricing and procurement practices

Unaffordable prices for medicines have become one of the most pressing concerns for patients and health systems in countries across the income spectrum. There is an unfortunate distortion of the market for medicines, as demand does not tend to depend on the price and vice-versa. This became all too apparent during the COVID-19

pandemic, as limited supply of essential health products led to concerning reports of hoarding and unaffordable pricing.

A further challenge for the global health product market is inherent in its fragmentation, which can lead to asymmetries of information. Sellers may include manufacturers, wholesalers, importers, pharmacies, online retailers and informal outlets, while buyers may include ministries of health, insurers, donors or individual households. Pricing information is often not transparent to all parties and, in certain cases, lower-income countries and small markets have been shown to be paying higher prices in both absolute and relative terms. As a result, many countries with limited resources resort to charging out-of-pocket payments to patients, representing a heavy financial burden.

As countries advance towards the goal of universal health coverage, budgets are becoming increasingly constrained, and governments and other payers have become more sensitive to pricing. In this context, they can no longer be passive payers and must become more active price negotiators and achieve better access for their populations. WHO works with countries to improve affordability to health systems and patients through recommending pricing policies for setting, managing, or influencing pharmaceutical prices (WHO, 2020). Pooled procurement can also involve formal agreements between purchasers within or between countries. WHO also offers a strong recommendation for promoting the use of quality-assured generic and biosimilar medicines, which can help shape market competition and pricing within and between countries to facilitate equitable access (WHO, 2020).

Despite such efforts, countries are still concerned about, “inequitable access to such products within and among member States,” and in 2019, they made commitments and requested WHO to improve the transparency of markets for health products (World Health Assembly, 2019). Work is in progress at WHO and other multilateral institutions to facilitate information-sharing (WHO, 2021a) and ensure that pricing policies and strategies are aligned with the goals of health security, fair access and affordability. A fair price must be affordable for health systems and patients while also providing sufficient incentive to invest in innovation and then in the production of medicines (BMJ, 2020).

Charting a path forward

A key aspect of universal health coverage is the right of everyone to access safe, quality-assured, effective, and affordable medicines when they need it, where they need it (World Health Organization Global Health Observatory, 2022). When medicines are found to be truly effective (WHO, 2021c), they must be made rapidly available to those who need them. While trade does contribute towards improving access to medical goods, current market rules do not facilitate the achievement of

equitable access to medicines and health products for all. The COVID-19 pandemic has highlighted more than ever that achieving this access requires collective effort from the global community and policies that facilitate availability and affordability must be the backbone of these efforts.

The ACT-A partnership, established early in the COVID-19 pandemic, has shown how close and continuous cooperation among international partners could organize and accelerate the development and delivery to novel technologies worldwide. Furthermore, the implementation of technical recommendations, based on scientific evidence, should be a driver for countries and national political commitment remains a prerequisite. Collaboration with regional economic communities is also a powerful strategy to ensure greater adhesion to technical guidance.

As part of the ACT-A partnership, the COVAX initiative has been working non-stop to address remaining delivery bottlenecks to achieving vaccine coverage in all countries. Getting through this pandemic and preparing better for the next one requires that work is carried out across the private and public sectors for the greater good. Currently, an intergovernmental negotiating body is discussing a pandemic treaty or another type of binding agreement to guide the world when the next pandemic occurs. In the interim, global and regional cooperation across intellectual property management, manufacturing and local production, regulatory reliance and harmonization, and pricing and procurement practices can facilitate equitable access to health products across conditions.

Lessons learned from the COVID-19 pandemic and beyond must be applied to address the fragilities that persist in the health product value chain, affecting citizens with any health condition. In the words of WHO Director General Dr Tedros Adhanom Ghebreyesus, “We all want a world in which science triumphs over misinformation; solidarity triumphs over division; and equity is a reality, not an aspiration...If that is the world we want, we must start working for that world now”(WHO, 2021b).

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