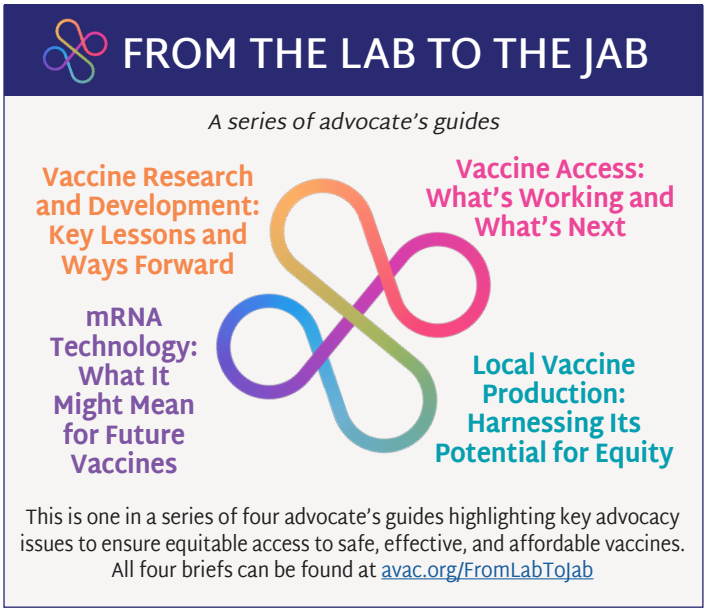
Vaccine Access: What's Working and What's Next

AVAC
Global Health Advocacy, Access & Equity

November 2023

Ensuring equitable access to safe, effective and affordable vaccines involves advocacy across multiple areas. This issue brief covers the web of issues that influence access to vaccines. It is one of a series of four issue briefs, which provide a roadmap for advocacy to advance the development of essential vaccines for HIV, COVID-19, tuberculosis, and other global public health threats, and approaches to ensure equitable access to these life-saving vaccines. Additional topics cover the research and development (R&D) process, the role of mRNA technology; and the need for local vaccine production.



Key Points

- Patents and other intellectual property (IP) barriers prevent registration, production, importation, and sales of affordable generic medicines and biosimilar products (versions of biologic products such as non-mRNA-based vaccines, monoclonal antibodies and insulin that are similar to branded products) in many countries.
- Regulatory barriers can delay access to vaccines and other medical products.
- Advocates have successfully used a range of measures and strategies to address IP, regulatory and other barriers, and ensured that their communities have information about the risks and benefits of vaccines and other medical products.

Vaccine Access

A web of issues influence access to vaccines. IP and regulatory barriers need to be overcome; countries need to have investments in, and the capacity, technology, and know-how for local vaccine production, and proven vaccines need to be incorporated into national guidelines.

Once vaccines are authorized to enter the market, countries need the policies, systems and human resources to get jabs into arms at scale. This includes the ability to maintain cold chains for transport and storage, train healthcare workers, and provide accurate, understandable information to communities. To enable sustainable local vaccine production, IP and technology must be shared, and major support must be provided for globalized vaccine manufacturing. These resources are essential to ensure access, uptake and, ultimately, public health impact from new vaccines.

Inequitable Global Access to Medical Products

Low- and middle-income countries (LMIC) have had to wait years—or even decades—for equitable access to essential, affordable vaccines and medicines, because their high prices were prohibitive. Until advocates made leaders listen, and pressured them to enable access to lower-priced generic antiretrovirals (ARVs), HIV treatment was unaffordable in LMIC, leaving millions of people to die needlessly.

Competition between generics manufacturers has lowered ARV prices, and HIV treatment access has steadily increased in LMIC, but competition is not the only way to achieve affordability and access. Decentralized and local production, with redundancy and complementarity, are also necessary for sustainability and equitable access.

FROM THE LAB TO THE JAB

R&D (research and development)

R&D covers discovery of a product, and pre-clinical to human trials. Advocates play an important role in R&D, ensuring that trials are designed to answer key questions in different populations, and that study volunteers are not subject to undue risks, and are able to make informed decisions about trial participation. Meaningful, consistent and sustained community engagement in R&D also ensures that products are relevant, acceptable, and trusted, and can increase access and uptake.

Intellectial Property (IP) Barriers

Patents and other IP barriers prevent generic and biosimilar versions of medicines and vaccines from being produced, registered, imported and sold in many countries; even where these products are available—high prices limit access. Advocates have successfully overcome IP barriers, and worked to improve national laws, including patent laws, to facilitate access.

Registration

To enter the market, pharmaceutical companies must register a product with national regulatory authorities (NRAs). This process can take years, especially in (LMIC), where NRAs often function with limited resources.

Adoption and Implementation of Products

To achieve impact, vaccines must be included into national and global guidelines, and countries need the infrastructure to maintain a cold chain for their storage and transport; healthcare workers must be trained, and people need to be offered clear and accurate information about their benefits and risks.

Advocates Role

Supporting the COVAX Facility: Pressuring governments to join the COVAX Facility (see further description below) to maximize purchasing power and ensure equitable access to safe and effective vaccines as soon as they receive regulatory approval, with a commitment to donate any surplus vaccine doses in their national stockpiles to the Facility.

Calling out vaccine nationalism: Highlighting the damaging impact of vaccine nationalism on global efforts to end the COVID-19 pandemic as quickly and humanely as possible.

Calling for accountability and transparency on public investments in vaccine R&D: Demanding greater government and private sector transparency on the use of public funds for R&D, pre-purchase agreements, and advanced market commitments for vaccines and pricing plans.

Advocating for equitable and transparent vaccine pricing: Ensuring that distribution criteria are ethical and rights-based, with consistent metrics for prioritizing populations for COVID-19 vaccination.

Demanding input from civil society on definitions for fair and equitable vaccine distribution: Insisting on participatory approaches and transparency to develop context-specific allocation frameworks.

Engaging in planning for vaccine deployment and health system readiness: Demanding that governments adequately fund vaccination programs and share national deployment plans with the public.

Access Barriers

Pharmaceutical companies are not transparent about product development costs; estimates range from $314 million to $2.8 billion for a drug, vaccine or biological product.[1] This amount includes opportunity cost (the potential profits that a company could have made from other investments), marketing and other costs.

The cost of goods sold (COGS) is used to estimate the total cost of manufacturing a product; it does not include R&D, marketing, and profit. For more information, see (https://avac.org/resource/cost-of-goods-sold-cogs-analyses-faq-brief/). Advocates can use COGS analyses as leverage to advocate for lower prices, and to estimate pricing for generic versions of medicines, biosimilar products and vaccines. (see Access Enablers, page 5).

Intellectual Property (IP) is one of the main barriers to affordable vaccines. It allows the original inventor or developer to control the market and set the price, even when governments have contributed to R&D costs - and even during a pandemic. Key IP issues (patents, patent linkage, trade secrets, and data exclusivity) are explained below.

Patents

Governments grant patents, which give the patent holder the right to prohibit others from making, using, and selling their products in a given country for a certain amount of time (usually 20 years), and the freedom to set prices for their product. Patents allow price gouging, and they also can delay or prevent access to essential vaccines and medicines in LMIC. For example, a generic medicine made in India cannot be sold in other countries where the medicine is patented.

Each country has its own patent laws, and products are patented on a country-by- country basis. Advocates have been working at the national level to improve patent laws, so that it is more difficult for pharmaceutical companies to get unmerited patents, and to extend the life of a patent through a process knowns as evergreening (which refers to minor changes or new formulations such as for a fixed-dose combination of existing ARVs, a new use for a product, or an extended-release version of a medicine).

To obtain a patent, certain criteria must be fulfilled; according to the World Intellectual Property Organization (WIPO), these criteria are:

- **Novelty**: the invention must be new—something that is not already known as part of the 'state of the art' (which is all existing knowledge in the field).
- **Inventive step**: the product must include an inventive step, which is not already obvious to people with skills in its technical area.
- **Industrial application**: the product can be used for an industrial or business purpose, or that it is useful.

Often, vaccines have multiple patents. Primary patents directly protect an active ingredient; secondary patents protect chemicals related to an active ingredient, methods of use, formulations, and dosages. For example, the mRNA-based COVID-19 vaccines have a web of patent protection, which includes the technology itself, the lipid nanoparticles (or tiny bubbles of fat that protect mRNA and deliver it into cells), and the verison of the spike protein that the vaccines target.

Patent linkage

In certain countries, the approval for generic and biosimilar versions of a branded product has been linked with its patent status. This means that generic and biosimilar producers cannot obtain marketing authorization until the patent has expired, or unless a NRA decides that a generic or biosimilar version of a branded product will not infringe on its patent – or that the patent is invalid.

Trade Secrets

Even when there are no patents, other IP barriers exist, such as data exclusivity (see below) and trade secrets– the knowledge that goes into product production, such as the recipe for Coca-Cola. For example, biosimilar manufacturers cannot access the full knowledge of a vaccine's production process, because it is protected by trade secrets. Without technology transfer, manufacturers may have to dismantle vaccines and analyze them before they can be reproduced (a process called reverse engineering, often requiring trial and error).

Data Exclusivity

Data exclusivity prevents producers of generic and biosimilar products from relying on the originator's registration data, including from clinical trials. Instead, these manufacturers must generate this data themselves (even when repeating clinical trials might be considered unethical). Data exclusivity protection can apply to patented and unpatented products, and after patents have expired. It can delay access to generic and biosimilar products for three to ten years.

Regulatory Barriers

NRA grant registration for medical products, enabling them to enter the market. In LMIC, this process may take years. This delay is caused by factors including slower regulatory processes, and by pharmaceutical companies, which tend to prioritize registration in countries where profits will be highest. This 'regulatory lag' delays access.

A study found that time-to-registration of 34 US FDA-approved products in countries hosting clinical trials took far longer in LMIC vs. high-income countries (HIC), with the least access in Africa. Five years later, only 5 of 19 drugs were registered in lower-middle-income countries hosting trials.[2]

Biologics/Biosimilars

Biologic products (monoclonal antibodies, insulin and non-mRNA-based vaccines) are large molecules produced from living sources, such as bacteria, yeast, and plant and animal cells. Biologics are more complicated to purify, process and manufacture than other medicines. Unlike small chemical molecules, it can be impossible to produce exact copies of biologic products. These inexact copies, which show no meaningful differences in safety and efficacy from the original reference pruduct, are called biosimilars.

Biosimilar product registration processes are not harmonized, and sometimes done on a case-by-case basis. Some NRA may require safety and efficacy trials of biosimilar products; as an example, if uncertainties remain after comparing a biosimilar product to its reference product in analytical, non-clinical and early-stage clinical trials, India's Central Drugs Standard Control Organization requires safety and efficacy trials.[3]

Delays in registration also occur because LMIC NRA lack resources, and they have redundant, non-transparent processes that are not aligned with international standards. This regulatory fragmentation delays access to vaccines and medicines.

There has been progress. Efforts are underway in many countries, often with support from the World Health Organization (WHO), to strengthen technical capacity of, and financing for, NRA, to speed up the approval process. The African Medicines Regulatory Harmonization Program is working to optimize NRAs by "...improving medicine registration processes and operational inefficiencies, thereby reducing registration times whilst enhancing the quality of the registration decision."[4]

Market Exclusivity

NRA can grant market exclusivity, which prevents registration of generic and biosimilar products, even when data on the original product is not needed, and in the absence of a valid patents. The length of market exclusivity varies, by country. For biologics, it is 12 years in the United States, and 10 years in the European Union.

Emergency Use Authorization (EUA)

During global health emergencies, NRAs can grant an EUA, allowing products that can diagnose, prevent and treat serious or life-threatening illnesses to become available more rapidly, such as COVID-19 vaccines and treatment. There are certain conditions for obtaining an EUA. These include the absence of adequate, approved or available options, and the scientific evidence supporting the product. Later, pharmaceutical companies can apply for full approval, but it is not always granted. Vaccines for COVID-19 were the first to be approved under EUA.

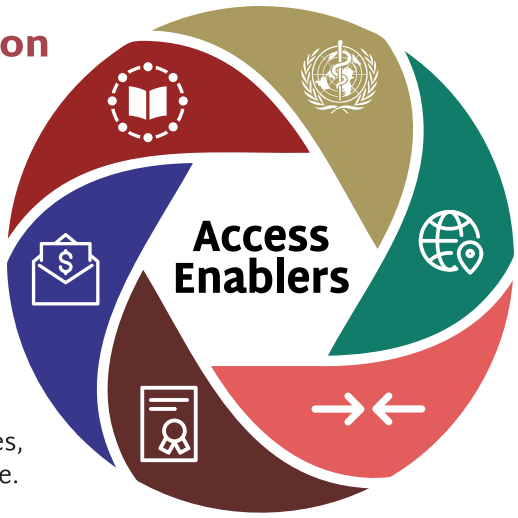
Access Enablers

WHO Guidelines and the Essential Medicines List (EML)

Advocates can push for inclusion of vaccines and other medical products into WHO guidelines and/or the EML and national guidelines.

Community Education and Advocacy

Sharing clear and accurate information about vaccine benefits and risks can mobilize people to demand access – and achieve it.



Addressing IP Barriers

Use the public health safeguards included in the Trade-Related Aspects of International Property Rights (TRIPS) Flexibilities.

Donations

Donations may be helpful for some countries, and under certain circumstances, but they are not sustainable.

Patent Oppositions

Advocates can oppose patents that do not meet national criteria; if the patent is rejected, governments can produce or import affordable generic biosimilar medicines.

Voluntary Access Mechanisms

A voluntary license (VL) is a legal agreement between patent-holding pharmaceutical corporations and manufacturers of generic and/or biosimilar products. A VL allows these manufacturers to produce and supply these products in some LMIC at a lower price than the originator product under certain conditions.

Community Education and Advocacy

It would be impossible to imagine the progress against HIV without the work of people living with and affected by HIV. Sharing clear and accurate information about vaccine benefits and risks can mobilize people to demand access – and achieve it.

WHO Guidelines and the Essential Medicines List (EML)

Advocates can use WHO guidelines and/or the EML as leverage for national-level access to vaccines and other medical products. WHO guidelines are evidence-based, and they include community values and preferences. These guidelines describe resource implications, and give attention to equity, human rights principles, gender and other social determinants of health, and define the standard of care for LMIC. Products are included in the WHO EML based on disease prevalence, public health relevance, efficacy, safety, and comparative cost-effectiveness.

Addressing IP Barriers

Trade-Related Aspects of International Property Rights (TRIPS) Flexibilities.

Some public health safeguards have been included in TRIPS, which is the World Trade Organization (WTO) multilateral agreement on IP. The 2001 *Doha Declaration*[5] recognized that "…. the TRIPS Agreement does not and should not prevent members from taking measures to protect public health…. we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." The *Doha Declaration* outlined specific flexibilities,[6] including that:

- Member states can grant a compulsory license (CL), under which third parties are allowed to produce a patented medicine or vaccine without the consent of the patent owner (although they are obliged to negotiate first, and pay royalties). However, countries that have issued a CL face backlash from pharmaceutical companies and HIC. Often, the threat of a CL leads to lower prices or inclusion in voluntary access schemes, such as voluntary licenses (VL). For example, when a country is not included in a VL, advocates have convinced their governments to grant a CL for a medicine. Sometimes, pharmaceutical companies expand their VL to include countries that have granted a CL, to discourage this practice.

- Parallel importing allows countries that are unable to manufacture pharmaceutical product to obtain cheaper generic and/or biosimilar versions produced elsewhere, if necessary.

The TRIPS Waiver

In October 2020, India and South Africa proposed a temporary waiver of certain TRIPS Agreement provisions, to enable access to COVID-19 vaccines, treatments and other medical products for at least three years (or the duration of the COVID-19 global health emergency). Most HIC opposed the waiver, to protect profits on their medical products, despite massive global advocacy, including from the People's Vaccine Alliance.

Lengthy negotiations led to a compromise in 2022, which only covered vaccines; it allows eligible countries that exported less than 10% of the world's vaccines in 2021 to issue a single authorization to waive multiple vaccine patents, including on ingredients and processes, and export vaccines to other eligible countries. Thus far, this provision has not been used, because it is very complicated. In addition, the compromise lacks a timeline and it adds new requirements before a country can exercise existing TRIPS flexibilities - which has greatly disappointed access advocates.

- Least-developed countries (LDC) can delay pharmaceutical patents until January 1, 2033 (if they are still LDC); if a medicine or vaccine is not patented in an LDC, the government does not need a CL to import it (although some VLs may prohibit manufacturers who have signed them from exporting their products).

Patent Oppositions (pre- and post-grant)

Patents that do not meet national patentability criteria can be opposed. Some countries allow patent oppositions to be filed before a patent has been granted (called a pre-grant opposition or a pre-grant observation), while others only allow oppositions on granted patents.

People and organizations can file a patent opposition, and many have done so successfully, saving millions of dollars for governments by enabling them to import affordable generic medicines and biosimilar products—and allowing them to expand coverage of medicines and vaccines. (For more information on the steps involved in filing a patent opposition, see https://www.patentoppositions.org/en/how_to_build_an_opposition/things_you_should_know).

Voluntary Access Mechanisms

Voluntary mechanisms rely on outside pressure on, and goodwill of, for-profit entities. The COVID-19 pandemic has made the limitations of voluntary mechanisms clearer, but these measures may be helpful for some countries, and under certain circumstances.

Voluntary Licenses (VL) and the Medicines Patent Pool (MPP)

VL are legal agreements between patent-holding pharmaceutical corporations and manufacturers of generic and/or biosimilar products. Under a VL, pharmaceutical corporations allow generic and biosimilar manufacturers to produce and supply a medical product, often for royalties of up to 10%. The pharmaceutical corporations also specify the conditions under which the product can be sold, and the countries it can be sold in. Sometimes a third party, such as the United Nations-backed Medicines Patent Pool (MPP), manages VLs, acting as a one-stop intermediary between patent holders and generics and biosimilar manufacturers. The MPP aims to ensure transparency of VLs, and for better terms and broader coverage, seeking to cover all products on the WHO Essential Medicines List.

While VLs can enable access, pharmaceutical corporations set the terms of these argeements. Many middle-income countries, especially upper-middle- income countries, are not included in VLs, because pharmaceutical corporations want to sell their products at high prices in these countries. The conditions in VLs are not always transparent, and they can include limits on who can purchase a product, how it can be used, and requirements for permission to conduct clinical trials. Usually, advocates and communities are not part of the time-consuming negotiations for bilateral VLs, limiting their opportunity to improve these agreements.

VLs can restrict the supply of active pharmaceutical ingredients (API), preventing producers in countries that are excluded from the VL from accessing those ingredients. Some VLs do not allow countries to make API, which forces them to buy it at a higher price – and charge more for their products. In some cases, VLs allow manufacturers to produce generic and biosimilar products, but not to have access to them domestically. For example, the VL for the HIV drug dolutegravir allows manufacturers in China only to produce and export the drug – not to provide it to people in their own country.[7]

Countries that are excluded from VLs have used strategies such as price negotiations, and, with support from advocates, threatening to—or granting—a CL, or opposing patents.

Donations

Pharmaceutical companies have donated vaccines and other medical products. These donations can meet urgent health needs and be lifesaving, but they are not assured—or sustainable. *WHO Guidelines for Medical Donations* states that, generally, "…medicine donations are neither a long-term solution to underfunded health systems nor a solution to the lack of access to medicines in poor countries…however, donations can be temporary solutions to defined problems."[8]

In addition, medical donations increase the workload for ministries of health and healthcare providers; sometimes donated products are not aligned with national guidelines, have unfamiliar trade names, or are close to expiry. In addition, donations are not always coordinated with recipients—who may have no way to store them.

The COVID-19 Vaccines Initiative (COVAX)

COVAX, an initiative co-led by the Coalition for Epidemic Preparedness Innovations, Gavi, WHO and UNICEF, aims to accelerate development and production of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world. It served as the vaccines pillar of the Access to COVID-19 Technologies Accelerator (ACT-A). As soon as COVID -19 vaccines became available, its main role became to pool procurement and supply vaccines to a wide range of LMIC. Initially, COVAX's target was to secure enough COVID-19 vaccines to achieve global coverage of 20% by the end of 2021. In October 2021, COVAX's target increased to 40% global coverage by the end of the year, and to 70% by mid-2022. COVAX was not able to achieve any of its targets, for reasons including:

- Lack of global cooperation: HIC hoarded vaccines for their own populations, rather than working through COVAX.
- The limited – and unpredictable—supply of vaccines, due to the unwillingness of pharmaceutical companies to their (prioritize their contracts) with COVAX.
- Delayed donations, many of which were near expiry.
- Lack of capacity in resource-limited settings to store, transport and administer vaccines.
- Misinformation-driven vaccine hesitancy.

Addressing Regulatory Barriers

Sometimes, regulatory barriers to medical products can be addressed through WHO prequalification (PQ). In participating countries, a collaborative registration process for WHO-prequalified products can lead to an NRA registration decision within 90 days. The Global Fund Against AIDS, Tuberculosis and Malaria's (GFATM) Expert Review Panel (ERP) can make products available in countries where they have not yet been approved by NRA.

WHO PQ

Producers of branded, generic and biosimilar products included in WHO guidelines can apply for prequalification, which is a four-step process that includes lab and site inspections, and assesses a product's safety, quality, and efficacy. WHO prequalification is faster for products that have been approved by certain NRA; otherwise, it takes an average of 17 months—and often much longer—and the process can be complex, redundant, and non-transparent. Recommendations have been developed to strengthen and streamline the process.[9]

GFATM External Review Pane (ERP)

The GFATM allows manufacturers to submit certain generic and biosimilar products for COVID-19, HIV, tuberculosis, viral hepatitis and malaria to the ERP, a group of independent experts who review

a product's potential risks and benefits and make reccommendations for their use. Once products are ERP-recommended, GFATM Principal Recipients can procure them.

Local Production

Enabling countries to make their own vaccines can ensure a sustainable supply, if IP and technology are shared, and with major support for globalized vaccine manufacturing. For more information, see the brief on local production and manufacturing in this series, https://avac.org/FromLabToJab/.

The mRNA Vaccine Technology Transfer Hub

The objective of the mRNA vaccine technology transfer hub is to build capacity for producing mRNA-based vaccines in LMIC. Afrigen, in South Africa, is developing the mRNA technology, based on publicly available information. Afrigen will work with a network of technology recipients (originally called "spokes", now renamed partners) in LMIC. Funded by a handful of mainly HIC goverments, WHO, with the MPP and the ACT-A/COVAX, provides training and funding for establishing and transfering production know-how, quality control and registration expertise.

Using Data on Cost of Goods Sold (COGS)

Some organizations and researchers produce information about the COGS for vaccines and other medical products, which has been very useful for advocates. For example, Public Citizen estimated that it would cost $23 billion to produce eight billion doses of an mRNA-based COVID-19 vaccine,[10] while Oxfam estimates that mRNA vaccines could be produced for $1. 18 per dose.[11] This information makes it difficult for pharmaceutical companies to justify pricing in the range of $ 20-30 – and sometimes far more—per dose, especially for products that were developed with government funding.

What Can Advocates Do?

There are many ways that advocates can—and have—successfully addressed access barriers.

CONDITIONS: Advocates can insist that pharmaceutical corporations that conduct research in their countries commit to providing their products to trial participants after the study ends, and ensure that they are available and affordable in these countries. Pharmaceutical corporations need to register their products promptly, produce at least some of them locally, and use other measures that enable access, such as VL and technology transfer. Pharmaceutical corporations that use government funding to develop vaccines and medical products should be required to provide pricing transparency, opportunities for negotiation, and other measures to ensure access, affordability, and technology transfer.

BUILDING DEMAND: community education—sharing information about new vaccines and other medical products—can mobilize people to pressure governments and pharmaceutical companies to provide access.

SPEAK OUT against vaccine nationalism and high-income country hoarding.

CALL FOR pricing transparency.

USE INFORMATION about vaccine production costs and government contributions to R&D to bolster the case for equitable access.

Continued on next page

MEANINGFUL CIVIL SOCIETY PARTICIPATION and engagement in decision making processes at national and global levels is essential. Community needs, values and preferences must guide national and global initiatives.

SUPPORT ACCESS INITIATIVES SUCH AS COVAX, the mRNA vaccine technology hub and advocacy campaigns.

PUSH FOR USE OF TRIPS FLEXIBILITIES: in LMIC, especially middle- and upper - middle-income countries that are excluded from VL. Advocate with governments, to encourage them to grant a CL, file patent oppositions, and work with local producers to expand access to vaccines.

LMIC-BASED advocates can work with their governments to identify, and work together to provide access to, patented vaccines (and other medical products) that meet their public health needs.

ADVOCACY FOR OPTIMIZING NRAs, so they have the necessary training, resources and processes for timely registration and oversight of vaccines and other medical products.

COORDINATION AMONG CIVIL SOCIETY. Creating and strengthening alliances and sharing information can strengthen effective access strategies.

Resources

- **THE AFRICAN MEDICINES REGULATORY HARMONIZATION PROGRAM**: information on what the program is, and what it does - https://amrh.nepad.org
- **AVAC**: ADVOCATE'S GUIDE TO COVID-19 VACCINE ACCESS https://www.avac.org/sites/default/files/resource-files/Advocates_Guide_to_COVID19_Vaccine_AccessD_11.11.2020_0.pdf
- **KNOWLEDGE ECOLOGY INTERNATIONAL**: public interest advocacy, such as addressing the problems of developing new medicines and vaccines - https://www.keionline.org/
- LAPaL,the Long-Acting Therapeutics Patents and Licences Database: provides information on technical features, development status and intellectual property status of selected long-acting therapeutics that could have health impact in low- and middle-income countries - https://lapal.medicinespatentpool.org/
- **MAKE MEDICINES AFFORDABLE**: information on what activists in LMIC are doing to improve access to medical products for HIV, TB, hepatitis C and COVID-19:- https://makemedicinesaffordable.org
- **MEDICINES PATENT POOL**: aims to increase access to lifesaving medical products for LMIC- https://medicinespatentpool.org/
- **MÉDECINS SANS FRONTIÈRES**: information on voluntary licensing- https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf
- **MedsPaL**: information on patents and licenses of certain HIV, hepatitis C, tuberculosis, and other essential medicines in LMIC- https://www.medspal.org/?page=1
- **PATENT OPPOSITION DATABASE**: information on filing patent oppositions, and database of international patent oppositions- https://www.patentoppositions.org/

Continued on next page

- **PUBLIC CITIZEN**: advocacy for affordable medicines - https://www.citizen.org/topic/safe-affordable-drugs-devices/
- **SOUTH CENTRE**: is the intergovernmental organization of developing countries that helps developing countries to combine their efforts and expertise to promote their common interests in the international arena, including access to medicines - https://www.southcentre.int/about-the-south-centre/
- **THIRD WORLD NETWORK**: TWN's mission is to bring about a greater articulation of the needs and rights of the peoples of developing countries, a fair distribution of world resources, and forms of development that are ecologically sustainable and fulfil human needs, including access to affordable medicines and treatment - https://www.twn.my/twnintro.htm
- **WIPO**: Information on patents and trade secrets- https://www.wipo.int/portal/en/
- **WTO**: The Doha Declaration explained, https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm

Footnotes

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7054832/
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8100865/ov/pmc/articles/PMC8100865/
[3] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0NA==
[4] https://amrh.nepad.org/who-we-are
[5] https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
[6] https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2010/chapter_11_2010_e.pdf
[7] https://msfaccess.org/sites/default/files/2020-11/HIV_Brief_Untangling-the-Web_2020.pdf
[8] https://www.who.int/publications/i/item/9789241501989
[9] https://www.ghtcoalition.org/documents/pdf/Navigating-complexity-to-improve-global-access-supporting-a-more-efficient-and-effective-WHO-prequalification-program.pdf
[10] https://www.citizen.org/article/how-to-make-enough-vaccine-for-the-world-in-one-year/
[11] https://www.oxfam.org/en/press-releases/vaccine-monopolies-make-cost-vaccinating-world-against-covid-least-5-times-more

About This Brief

AVAC gratefully acknowledges many friends and colleagues as we researched and developed *From the Lab to the Jab* series. It was written by Tracy Swan, in collaboration with AVAC staff. Special thanks to Luz Marina Umbasia Bernal, Cindra Feurer, Gregg Gonsalves, Laia Ruiz-Mingote, Tom Rogers Muyunga-Mukasa, Paul Sixpence, Bill Snow, and Els Torreele. This publication was made possible with support from the Bill & Melinda Gates Foundation, the New Venture Fund, and PEPFAR through the United States Agency for International Development (USAID) with their support of the Coalition to Accelerate and Support Prevention Research (CASPR). AVAC does not accept funding from the pharmaceutical industry.

About AVAC

AVAC is an international non-profit organization that leverages its independent voice and global partnerships to accelerate ethical development and equitable delivery of effective HIV prevention options, as part of a comprehensive and integrated pathway to global health equity. Follow AVAC on Twitter @HIVpxresearch; find more at www.avac.org, www.prepwatch.org and www.stiwatch.org.