Equitable Access Contracts: Building Blocks of a Future Global Vaccine Strategy

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Introduction

Due to the major legal gaps revealed in the course of the Covid-19 pandemic, in December 2021, WHO member states decided to establish an intergovernmental negotiating body (INB) to negotiate a new agreement on pandemic preparedness and response. On 5-7 December 2022 the INB held its third meeting, at which a conceptual zero draft (hence force, "draft pandemic treaty") was considered.

Among the innovations introduced by the draft pandemic treaty, making vaccines fairly and equally available in high income and low and middle income countries (LMICs) is a central principle (Article 4) and obligation (Chapter 3).

The purpose of this note is to highlight the importance of contracts in operationalizing this principle and obligation in practice. Of particular importance are two kinds of contracts: first, funding contracts between philanthropic organizations or governments and vaccine developers ("funding contracts"), and second, voluntary intellectual property (IP) licensing and technology transfer contracts (in short, "technology transfer contracts") between vaccine developers and manufacturers in LMICs. Developing a coherent and consistent global approach through international best practices – which would guide contract drafters as to equitable access provisions (voluntary licensing, technology transfer, affordable pricing etc.) to be included in such contracts – are desired.

The Problem

Covid-19 vaccines were developed at an astounding speed, yet there was a major gap between access to vaccines in high income versus low- and middle-income countries (LMICs). High income countries concluded Advanced Purchase Agreements (APAs), purchasing, early in the pandemic, most of the global vaccine supply. In contrast, LMICs did not have the money to commit early on to purchase vaccines through APAs. While trade restrictions and supply chain problems also restricted access, the fact that only high income countries and a few middle-income countries manufactured vaccines, with no manufacturing in low-income countries, severely limited the global supply. CEPI, WHO and GAVI established COVAX, an international procurement agency whose main purpose was to provide vaccines to LMICs (as well as to provide an insurance to high income countries), but high income countries bought up most of the supply, and COVAX failed to achieve its vaccination goals.

The Covid-19 pandemic thus revealed a major gap between high income and LMICs in the timely access to vaccines and other medical countermeasures. This gap is widely recognized, and as a result, the draft pandemic treaty currently under discussion at the WHO, defines equity in access to vaccines and other medical products as a basic principle (Article 4) and obligation (Chapter 3).

Within international law circles, matters of access to medicines have historically been discussed in the context of the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health. The Covid-19 pandemic has been no different. As patent protections prohibit the copying of newly developed vaccines, critics have blamed IP rules for the delays caused. To overcome this barrier, South Africa, India and other countries proposed a TRIPS waiver regarding Covid-19 related health products. Their proposal was opposed by high income countries whose pharmaceutical industries aggressively protect the patents of their medical inventions. Ultimately, a limited TRIPS waiver has been adopted, which applies to vaccines only (but not to therapeutics and diagnostics).

Yet even if the TRIPS Agreement is waived and/or patent protections not enforced, this alone will not achieve the desired goal of timely, fair and equitable access to vaccines in LMICs. Why is that the case? Because, first, in most LMICs, patent applications have not been filed. Second, the main bottleneck in LMICs is the lack of local manufacturing capacity. In contrast to medicines which are chemical compounds and thus relatively easy to replicate, vaccine production is a complicated process which requires specialized facilities, trained staff and know-how. Moreover, most LMICs lack the regulatory capacity needed to approve newly developed vaccines or to oversee their good quality production.

Increasing Local Manufacturing Capacity

The need to increase manufacturing capacity in LMICs for vaccines, therapeutics and diagnostics and other essential medical products, as well as personal protective equipment is now broadly recognized –including in Article 7 of the proposed draft pandemic treaty –as key for improving supply and therewith timely, fair and equitable access during the next pandemic. The EU has stressed the need for "enhancing the availability, access to, and affordability, of medical countermeasures, including by… providing incentives to increase regional manufacturing capacity for vaccines, therapeutics and diagnostics and other essential medical products, as well . And at the WHO special session, many LMICs submitted proposals for facilitating local production and technology transfer.

In building a future global vaccine strategy which advances timely and affordable access to vaccines, the key question, therefore, is: how do we sustainably increase manufacturing capacity in LMICs? The Global Health Innovation Access Alliance (GHIAA) in their report on "Strategic Insights for New Vaccine Manufacturing Initiatives" list the main strategic areas and resources that need to be developed, and include facilities,

equipment, raw materials, packaging materials, human resources, patent rights, know how, data and procedures, quality management and regulatory strategy; and a durable market for the vaccines produced.

To develop such manufacturing capacity, the conclusion of what is colloquially referred to as “technology transfer contracts”, that is, contracts between vaccine developers (in high income countries) and local manufacturers (in LMICs) that provide voluntary patent licenses and transfer technological know-how (and/or additional required procedures, quality management and regulatory support), are viewed by many as key building blocks of a global vaccine strategy. During Covid-19, only very few companies concluded such technology transfer agreements.

Moreover, including equitable access provisions in contracts between philanthropic foundations or governments and vaccine developers (in high income countries) such that R&D and innovation funding (rather than just end product vaccines) , is also increasingly seen as key, including under Article 8 in the draft pandemic treaty. During the Covid-19 pandemic, only some philanthropic organizations linked equitable access to funding, whereas governments (such as the U.S. Operation Warp Speed), did not.

Private contracts between global health actors are thus an important part of a future global vaccine strategy. What should be the key elements of such contracts if they are to advance equitable access?

Key Features of Contracts Advancing Equitable Access

To identify key issues we can draw on diverse sources: The Global Healthcare Innovation Alliance Accelerator (GHIAA) has created the Master Alliance Provisions Guide (MAPGuide), an open access tool assembling global health contracts obtained through diverse, mostly public sources (such as SEC filings). It identifies issues that need to be included in global health contracts for enabling increased access to medical products. Further, some philanthropic organizations have issued equitable access policies, such as the CEPI’s Equitable Access Policy, DNDi’s Intellectual Property Policy, GHIT Product Access Policy and the Bill and Melinda Gates Foundation Global Access Policy. These policies condition funding to developers on adherence to equitable access requirements. For example, CEPI concluded over 15 vaccine development agreements which integrated their equitable access policy, such as its contracts with AstraZeneca and Novavax.

Moreover, some universities have issued policies to promote equitable access to medical products through voluntary licensing. Notable examples are the COVID-19 Technology Access Framework, developed by Harvard, MIT and Stanford, and the AUTM Covid-19 Licensing Guidelines. Finally, there over 300 contracts between vaccine developers and local manufacturers providing voluntary licensing and undertaking at least some level of technology transfer. While most are confidential, we can draw from the few that have been publicly available.

While not a comprehensive list, drawing on the above sources, some key matters that should be addressed in funding and/or technology transfer contracts to advance equitable access are:

1. Defining Equitable Access Parties need to define what equitable access means under the contract. CEPI's– Valneva, Chikungunya Vaccine Funding Agreement provides an example.

2. Voluntary, non-exclusive licenses and affordable, sustainable pricing: When a license contract is concluded between a developer and local manufacturer, the parties need to determine a royalty and pricing mechanism such that the manufacturer can or must sell the vaccine at an affordable price in LMICs.

For example, under the COVID-19 Technology Access Framework and the AUTM Covid-19 Licensing Guidelines, developers agree to provide voluntary, non-exclusive and royalty free licenses to manufacturers. In exchange, manufacturers are expected to sell the medicines at no profit/no loss prices in LMICs during the pandemic. This was the approach followed in the Baylor College of Medicine contract with Incepta Vaccine, a local Bangladesh manufacturer.

Similarly, under CEPI's Equitable Access Policy, the IP of the product which CEPI supported belongs to the developer, but the developer is required to sell the vaccines at an affordable price. Accordingly, CEPI required AstraZeneca to sell on a no-profit, no loss basis during the COVID-19 pandemic. In turn, AstraZeneca provided a voluntary license to the Serum Institute in India, under which the vaccine would be made widely available to LMICs at no profit. Similarly, the GHIT Fund Product Access Policy requires grant recipients to give royalty-free licenses to manufacturers operating in least developed countries and that prices need to be set on the basis of no gains/no loss. The CEPI Chikunguya contract also differentiates between pricing in LMICs and other countries.

Further examples are MSD and Pfizer's licensing contracts with the Medicines Patent Pool under which their medicines would be sold royalty-free during the pandemic, and thereafter at 5% to public institutions and 10% to commercial bodies.

3. Technology Transfer: To enable sufficient manufacturing and equitable access in LMICs, in come contracts, CEPI requires developers to undertake technology transfer to local manufacturers and provides the funds to that end. For example, CEPI funded AZ's technology transfer of vaccine production to additional manufacturing sites. CEPI also funded the technology transfer by Novavax to manufacturers in Asia.

Moreover, some agreements include detailed technology transfer plans. For example Sanofi – Translate Bio, Influenza and COVID-19 Vaccine Collaboration & License Agreement. AstraZeneca's contracts with the Serum Institute and Ficoruz provided exclusive licenses to the manufacturer in the territory (India and Brazil, respectively), determined that pricing must be set at no profit/no loss in LMICs, and provided Ficoruz a

detailed technology transfer plan. It also included the resources that AZ had to provide Ficocruz (such as starting materials or providing manufacturing and release testing processes).

4. Regional or Multilateral Approach: Most voluntary licensing and tech transfer is bilateral, increasing production capacity in one manufacturer. Instead, we should be encouraging sharing through regional or multilateral patent pools and technology transfer hubs, such as through the Medicines Patent Pool and the mRNA vaccine technology transfer hub in South Africa. Examples include Pfizer's or MSD's licensing agreements with the MPP.

5. Regulatory Approval: Manufacturers need to receive regulatory approval from local authorities for the products. Contracts should address which party is responsible for obtaining them. For example, in AstraZeneca's technology transfer contract with Ficoruz, the latter is responsible for all regulatory approvals but AZ will supply the licensed know-how required therefore.

6. Timely Supply Commitments: Contracts should address the target markets for product supply, what volume will be supplied and when. For example, under AstraZeneca's technology transfer agreement with Ficouruz, AZ transferred a free, exclusive license to sell on the Brazilian market only.

Conclusion

Funding and technology transfer contracts are a key feature of a future global vaccine strategy. The above identified elements are drawn from fragmented practice. To develop a coherent and consistent approach, international best practices and/or model language for including equitable access provisions in contracts could be developed. This could be done alongside the pandemic treaty negotiations by organizations like CEPI (who have already developed such policies), the WHO and industry partners. The next pandemic is only a matter of time, and it is key that we start developing this legal infrastructure as part of better pandemic preparedness.