

**Report of the Task Force on  
Voluntary Licensing and Access to Medicines**

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This project and the associated Report would not have been possible without the leadership and inspiration of John C. Martin or the financial support of the foundation that bears his name.

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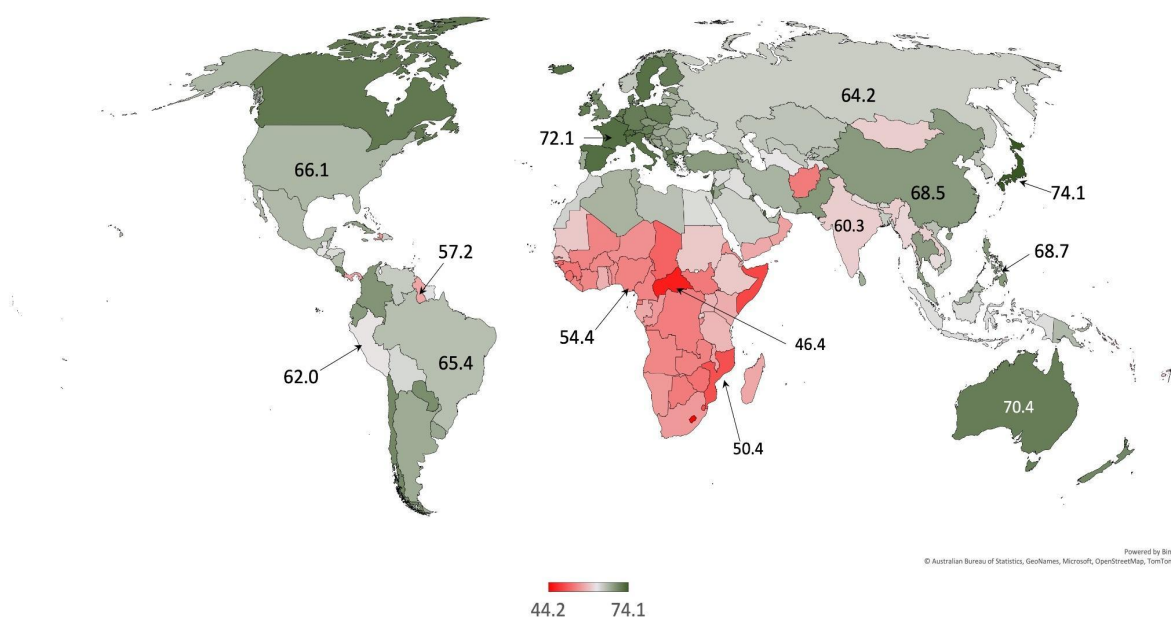
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## Introduction

Low and middle-income countries (LMICs) currently bear greater disease burdens than upper-income countries (UICs). The inequality is extreme with respect to infectious diseases such as tuberculosis, HIV/AIDS, and malaria and only slightly less so with respect to respiratory infections such as influenza and pneumonia.<sup>1</sup> It is commonly thought that the inequality is less severe with respect to non-communicable diseases (NCDs). Indeed, if one measures burdens by Disability Adjusted Life Years per capita, upper-income countries suffer even more from many NCDs than do LMICs. However, once the NCD data are adjusted to control for differences in the age distribution of each country's population, upper-income countries once again have the advantage.<sup>2</sup>

The inequality in disease burdens, in turn, is the principal cause of persistent inequality in life expectancy. The following map, constructed using the most recent comprehensive data from the World Health Organization, makes the differences among countries evident.<sup>3</sup>

Figure 1: Healthy Life Expectancy (HALE) at Birth (2019)



(To facilitate application of this key, we have provided the relevant numbers for a few representative countries.)

<sup>1</sup> See WHO, "Global Health Estimates 2019: Estimated Deaths by Age, Sex and Cause," (Geneva 2020).

<sup>2</sup> See *ibid.*

<sup>3</sup> All data were derived from WHO, "Healthy Life Expectancy at Birth," (Geneva 2020). Because the data were gathered in 2019, they do not reflect the impact of the ongoing COVID-19 pandemic. Initially, the pandemic hit upper-income countries harder than LMICs and therefore mitigated the disparity shown in the map – but the mitigation now appears to have ended. See, e.g., Nadia A. Sam-Agudu et al., "The Pandemic Is Following a Very Predictable and Depressing Pattern," *The Atlantic*, March 4, 2022.

Among the many factors contributing to these inequalities, one of the most troubling is the disparity in access to pharmaceutical products capable of preventing, managing, or curing serious diseases. That disparity is greatest concerning products that have been developed recently and thus are typically subject to intellectual-property protection.

Three considerations should prompt us, collectively, to support efforts to eliminate the inequality in access to medicines between UICs and LMICs. The first is a moral, humanitarian imperative: all persons in the world should have access to drugs that can alleviate their suffering and protect them against premature death. The second is that the current limits on access to life-saving medications in LMICs permit pathogens to spread and mutate, which endangers global health.<sup>4</sup> The third consideration is the economic benefit resulting from healthier populations and the opportunities arising for both the affected countries and their current and prospective trading partners due to increased production, consumption, and commerce.<sup>5</sup>

In recent years, pharmaceutical firms, governments, non-governmental organizations (NGOs), and scholars have used or advocated several strategies to increase drug availability in LMICs and thus reduce inequality. Such strategies include:

- 1) Donations of finished pharmaceutical products to the governments or populations of LMICs;<sup>6</sup>
- 2) IP pledges (promises made by IP holders to limit enforcement of their intellectual-property rights);<sup>7</sup>

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<sup>4</sup> The premier example of this hazard is the continued proliferation of variants of the COVID-19 virus, accelerated by low levels of vaccine distribution in developing countries. See, e.g., OECD, "Coronavirus (Covid-19) Vaccines for Developing Countries: An Equal Shot at Recovery" (2021), <https://www.oecd.org/coronavirus/policy-responses/coronavirus-covid-19-vaccines-for-developing-countries-an-equal-shot-at-recovery-6b0771e6/>.

<sup>5</sup> See, e.g., Hans Rosling, TED Talk: New Insights on Poverty (2007), [https://www.ted.com/talks/hans\\_rosling\\_new\\_insights\\_on\\_poverty?language=en](https://www.ted.com/talks/hans_rosling_new_insights_on_poverty?language=en).

<sup>6</sup> Two examples: A public-private partnership of USAID and a consortium of pharmaceutical firms (Eisai, GlaxoSmithKline, Merck, Johnson & Johnson, and Pfizer) donate drugs to address neglected tropical diseases (NTDs) in USAID-supported countries. See USAID Drug Donation Partnerships, available at <https://www.neglecteddiseases.gov/about/drug-donation-partnerships/>. Pfizer has donated products containing its antibiotic Zithromax to the International Trachoma Initiative, which has contributed to dramatic reductions in the incidence of trachoma (a leading cause of blindness). See World Health Organization, "Trachoma Elimination: Millions More to Benefit from Donated Azithromycin" (2022), <https://www.who.int/news/item/23-06-2022-trachoma-elimination--millions-more-to-benefit-from-donated-azithromycin>.

<sup>7</sup> Two examples: AbbVie announced its intention to dedicate to the public its intellectual property related to Kaletra, and Moderna announced that it will not enforce its "COVID-19 related patents against those making vaccines intended to combat the pandemic" – although the latter may be unstable. See Jorge L. Contreras, "No Take-Backs: Moderna's Attempt to Renege on its Vaccine Patent Pledge," Aug. 29, 2022, available at <https://blog.petrieflom.law.harvard.edu/2022/08/29/no-take-backs-modernas-attempt-to-renege-on-its-vaccine-patent-pledge/>. Universities also sometimes employ this strategy. For example, In April 2020, several universities publicly pledged to make their IP widely available for use in the COVID-19 response (e.g., the "COVID-19 Technology Access Framework" introduced by Harvard University, Stanford University, and the Massachusetts Institute of Technology). See Stanford Off. Tech. Licensing, COVID-19 Technology Access Framework,

- 3) Differential pricing (selling drugs in LMICs at prices below those charged in UICs);<sup>8</sup>
- 4) Voluntary licensing (contracts freely entered into by IP holders and generic manufacturers, in which the former authorize the latter to produce versions of innovative drugs and then to sell them in specified LMICs);<sup>9</sup>
- 5) Compulsory licensing (edicts by governments authorizing generic manufacturers to produce and versions of patented drugs and either to sell them domestically or to export them to LMICs, while paying modest royalties to the patentees);<sup>10</sup>
- 6) Parallel importation (importation by LMICs of lower-priced pharmaceutical products from other countries);<sup>11</sup>
- 7) Price controls (both direct and through the use of reference pricing);<sup>12</sup>
- 8) Reimbursement policies (which both put downward pressure on prices and limit the expenditures of public-health departments); and
- 9) Expropriation (compulsory acquisition by governments of IP rights, followed either by governmental manufacturing of the drugs covered by those rights or by the issuance of licenses to generic manufacturers to produce drugs for public use).<sup>13</sup>

Each of these initiatives has been beneficial. However, even in combination, they have failed to overcome the significant inequities in access to crucial medicines.

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<https://otl.stanford.edu/covid-19-technology-access-framework>. To date, there are 21 additional signatories to this pledge.

<sup>8</sup> For a recent, large-scale example of this approach, see “Pfizer Launches ‘An Accord for a Healthier World’ to Improve Health Equity for 1.2 Billion People Living in 45 Lower-Income Countries,” May 25, 2022, <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-launches-accord-healthier-world-improve-health>.

<sup>9</sup> The organization that, to date, has used this strategy most heavily and effectively is the Medicines Patent Pool (MPP). Details concerning the MPP are presented in Section I.B., below.

<sup>10</sup> Immediately after the turn of the century, compulsory licenses were used reasonably often. Since then, however, their usage has been episodic. The most comprehensive data concerning their incidence can be found at: Medicines Law & Policy, “The TRIPS Flexibilities Database,” <http://tripsflexibilities.medicineslawandpolicy.org/>. For slightly different estimates, see Ellen ’t Hoen et al., “Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016,” *Bulletin of the World Health Organization* 96 (2018): 188.

<sup>11</sup> See Jennryn Wezler, Mihir Mankad, and Adam Burrowbridge, “Program on Information Justice and Intellectual Property: Timeline for Us-Thailand Compulsory License Dispute,” (2009), <http://infojustice.org/wp-content/uploads/2012/11/pijip-thailand-timeline.pdf>.; Paul Champ and Amir Attaran, “Patent Rights and Local Working under the WTO Trips Agreement: An Analysis of the U.S.-Brazil Patent Dispute,” *Yale Journal of International Law* 27 (2002).; Nunn, A.S. et al., “Evolution of antiretroviral drug costs in Brazil in the context of free and universal access to AIDS treatment,” *PLOS Medicine* (2007), available at: <https://journals.plos.org/plosmedicine/article?id=10.1371%2Fjournal.pmed.0040305>

<sup>12</sup> As of 2015, over 30 LMICs either capped the prices at which specific pharmaceutical products could be sold or capped the markups that could be made on such products. See WHO, “Guideline on Country Pharmaceutical Pricing Policies,” (2015), 8, 18.

<sup>13</sup> See Hannah Brennan et al., “A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health,” *Yale Journal of Law and Technology* 18 (2016).

In the judgment of the members of this Task Force, voluntary licensing (the fourth of the strategies listed above) has not been used as often as it could or should be. More extensive deployment of this approach, we believe, could substantially reduce the current inequalities in access to medicines and thereby save many lives. That belief is rooted in experience; two members of the Task Force were responsible for promoting and managing the extensive use of voluntary licensing by Gilead Sciences that began in 2006. During that process, they learned many lessons, some of them painful. Those lessons are interwoven in this Report with insights and recommendations gleaned from the growing literature pertaining to health inequalities and access to medicines.

By advocating greater use of VLs, we do not mean to suggest that this strategy is a panacea. Even if used often, it would do little or nothing to address some dimensions of the ongoing global health crisis. For example, it would not materially increase research and development (R&D) on therapies for diseases that are prevalent in LMICs but are rarely contracted by residents of UICs. However, used thoughtfully, an expansion of VLs could save many more lives and avoid much misery.

Our support of these propositions begins in Part I, where we provide examples of uses of VLs to date, paying special attention to the programs developed by Gilead Sciences, Inc. In Part II, we present some general lessons distilled from that history. Part III presents a checklist of specific recommendations concerning how voluntary licensing might be used to greater effect in the future. Finally, in Part IV, we summarize the potential benefits of VLs and the impediments that must be overcome to secure them.

## **I. Voluntary Licenses in Practice**

Pharmaceutical firms routinely enter into license agreements with other parties. We are concerned here only with a subset of those agreements: licenses whose primary purpose is to reduce global health inequality by increasing the availability of medicines to the populations of LMICs. For simplicity, we will refer to them as “voluntary licenses” or “VLs,” for short.

Section A, below, summarizes the deployment of this strategy by Gilead Sciences. Sections B and C discuss its deployment by the Medicines Patent Pool (MPP) and the COVID-19 Technology Access Pool.

### **A. Gilead Sciences**

#### **1. HIV**

The virus that causes AIDS may have been transmitted from chimpanzees to humans in the early 20<sup>th</sup> century in what is now the Democratic Republic of Congo, but it first had a major impact on human populations in approximately 1980. Between that date and the turn of the century, the rate of new infections increased steadily, peaking at approximately 3.2 million per year. Despite enormous investment in research, there still exists no effective vaccine for the virus and no cure



for the disease.<sup>14</sup> However, beginning in 1987, a series of increasingly effective antiretroviral drugs (and combinations thereof) were developed by pharmaceutical firms and approved by regulatory agencies, making it possible for infected persons to survive and to live normal lives.<sup>15</sup> Figure 2 shows the dates on which the major drugs were introduced.

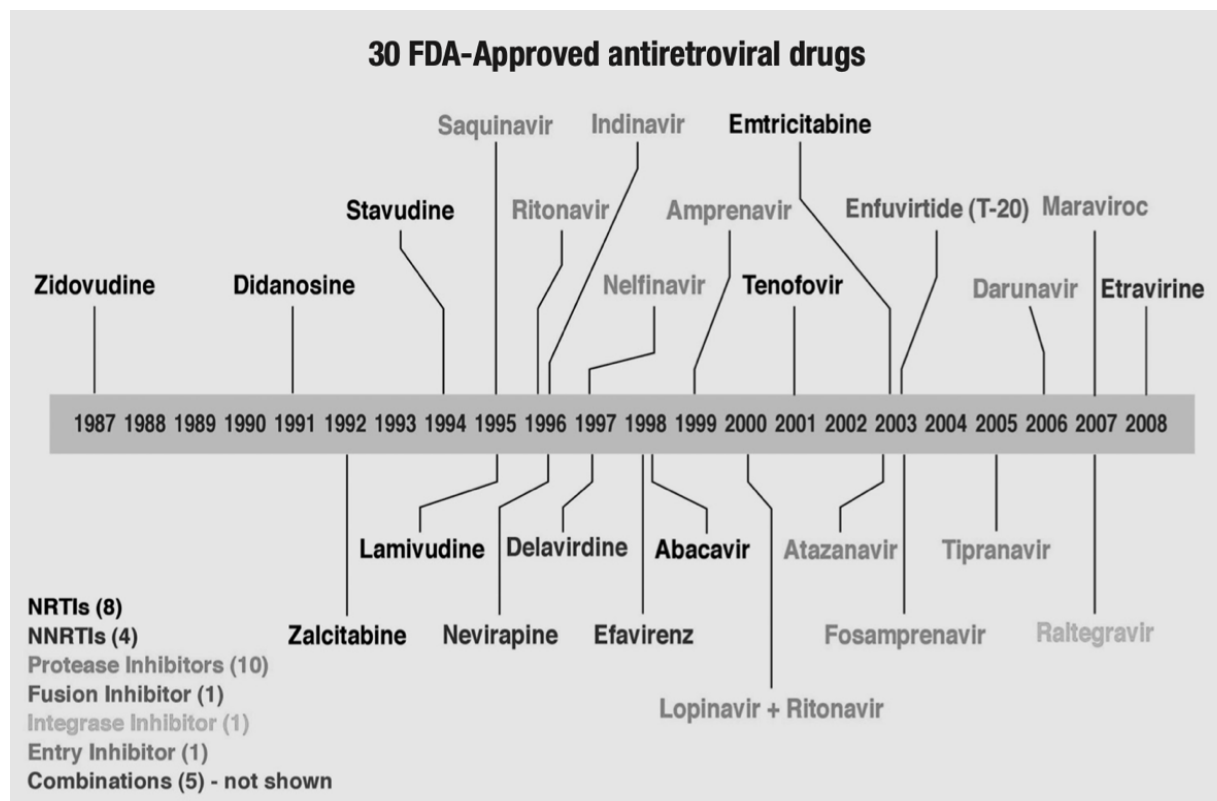


Figure 2<sup>16</sup>

From the beginning of the AIDS pandemic, the large majority of infected persons were located in LMICs, most of them in sub-Saharan Africa. However, the prices at which the ARVs were first introduced (typically between US\$10,000 and US\$15,000 per year for an adult patient) made them unaffordable for patients in those countries or for the countries' public-health services. As a result, the death rates from AIDS in LMICs continued to rise rapidly even after ARVs became available, provoking intensified demands that the companies holding the IP rights to the drugs lower their prices. A series of events in the 1990s reinforced those demands: several

<sup>14</sup> See Apoorva Mandavilli, "The Only H.I.V. Vaccine in Advanced Trials Has Failed. What Now?," *New York Times*, January 18, 2023.

<sup>15</sup> These medicines are most commonly known as "anti-retroviral" drugs (ARVs), less commonly as "antiretroviral therapies" (ARTs) or "highly active antiretroviral therapies" (HAARTs). The most effective are reverse transcriptase inhibitors, which impede the process by which modified DNA is generated from HIV RNA. See MSF, "Untangling the Web of Antiretroviral Price Reductions," (2020).; Clinton Health Access Initiative, "HIV Market Report: The State of HIV Treatment, Testing, and Prevention in Low- and Middle-Income Countries," (2019).

<sup>16</sup> Source: Lucia Palmisano and Stefano Vella, "A Brief History of Antiretroviral Therapy of HIV Infection: Success and Challenges," *Ann Ist Super Sanità* 47, no. 1 (2011).

pharmaceutical firms attempted to prevent South Africa from importing ARVs from other countries or imposing a compulsory license on their patents, which produced a public-relations backlash;<sup>17</sup> generic drug manufacturers in India (where patents on pharmaceutical products were not available until recently) began producing ARV cocktails and selling them cheaply in other countries;<sup>18</sup> and the government of Brazil used its bargaining power to extract major price concessions from some of the pharmaceutical firms, which in turn enabled it to curb the HIV pandemic in that country.<sup>19</sup>

Into this fray entered the fledgling company, Gilead Sciences. Between its founding in 1987 and 2000, Gilead had developed drugs in a wide variety of sectors. After the turn of the century, it concentrated on antiviral drugs. Tenofovir, Gilead's pioneering HIV treatment, received FDA approval in 2001 and other ARVs soon followed. As the effectiveness of these drugs became apparent, AIDS activists began to demand that Gilead devise a way of making them available in LMICs. The CEO, John C. Martin, took action and created the first rendition of Gilead's Access Program.<sup>20</sup>

A crucial complement to the company's efforts was the sudden availability of a massive amount of public funding to curb the pandemic. The principal sources of the money were the Global Fund to Fight AIDS, TB, and Malaria (launched in 2002) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR, launched in 2003). The sums that those programs in combination made available are shown in Figure 3. These funds not only procured medicines but augmented capacity via infrastructure and medical expertise, in the most affected countries.

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<sup>17</sup> See William Fisher and Cyrill P. Rigamonti, "The South Africa Aids Controversy: A Case Study in Patent Law and Policy," *Harvard Law School Case Study* (2005), <https://cyber.harvard.edu/people/tfisher/South%20Africa.pdf>.

<sup>18</sup> See AVERT, "Antiretroviral Drug Prices," <http://www.avert.org/antiretroviral-drug-prices.htm>.

<sup>19</sup> See Adele S. Benzaken, Gerson F.M. Pereira, and Lendel Costa, "Antiretroviral Treatment, Government Policy and Economy of Hiv/Aids in Brazil: Is It Time for HIV Cure in the Country?," *AIDS Research and Therapy* 16, no. 19 (2019).

<sup>20</sup> "The Gilead Access Program was created in consultation with experts and advocates, with the objective of making Viread available where the need is greatest and in a way that best addresses the treatment landscape in the developing world..." <https://www.gilead.com/news-and-press/press-room/press-releases/2003/4/gilead-launches-access-program-to-provide-anti-hiv-therapy-viread-in-68-developing-countries-at-no-profit>.

## HIV Funding from Donor Governments, 2002-2021, In Billions

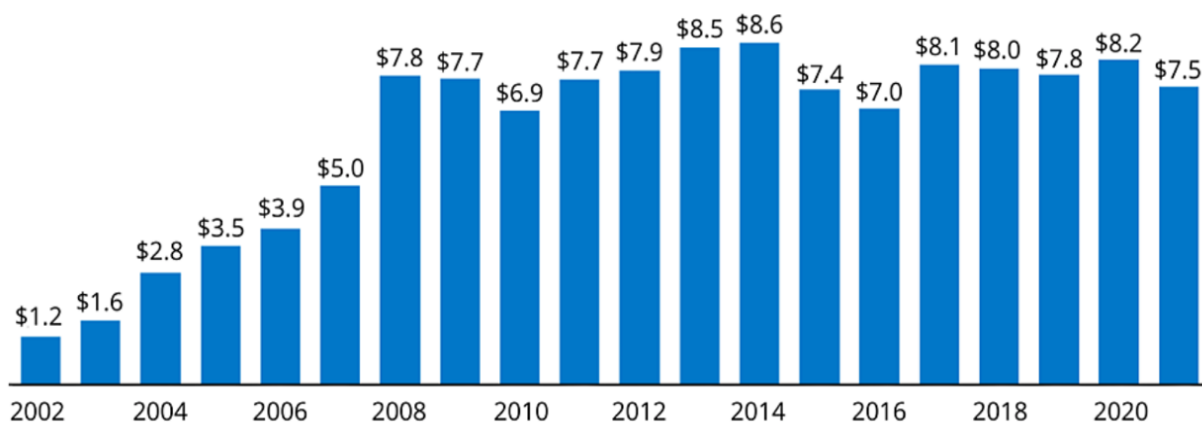


Figure 3<sup>21</sup>

Despite the magnitude of these funds, it quickly became apparent that, if Gilead wished to reach the rapidly growing population of infected persons in LMICs, it would have to lower the prices of its products in those countries. Starting in 2003, the company tried to do so by distributing its own branded products in those markets at no-profit prices.<sup>22</sup> Other companies with ARVs, such as Merck and GlaxoSmithKline, adopted similar “tiered” pricing policies for their branded products at the same time. The results were disappointing; too few buyers could afford the branded products manufactured by Gilead – even at no-profit prices.

Accordingly, in 2006, Gilead shifted to a strategy that added a crucial new component, voluntary licensing. Through a series of bilateral contracts, it authorized trusted generic manufacturers to produce and sell its HIV drugs in designated countries in Africa, South and Southeast Asia, Latin America and the Caribbean.

Among the central features of Gilead’s VL approach were:

- Licensees authorized to develop tenofovir, all tenofovir combinations, and all future pipeline HIV products;
- Low royalties – typically 5% of the licensees’ sales on their finished products;
- Royalties waived on pediatric formulations;

<sup>21</sup> Source: KFF and UNAIDS, “Donor Governments Spent US\$7.5 Billion on Efforts to Combat HIV/AIDS Globally in 2021, Largely Flat Amid the COVID-19 Pandemic, KFF-UNAID Report Finds” (July 22, 2022), <https://www.kff.org/global-health-policy/press-release/donor-governments-spent-us7-5-billion-on-efforts-to-combat-hiv-aids-globally-in-2021-largely-flat-amid-the-covid-19-pandemic-kff-unaid-report-finds/>.

<sup>22</sup> More specifically, Gilead selected 11 distributors, which it then authorized to sell its branded ARVs in 130 low-income and emerging economies. Gilead charged the distributors no-profit prices, but allowed them to earn profits of 10 to 15% to cover the costs of registering the products in those countries and cultivating the local medical networks.

- Right to manufacture, transfer, and to distribute within an agreed area (for HIV, the area covered 68 countries in 2003, increased to 95 countries in 2007, and ultimately encompassed 116 countries);
- Provisions forbidding diversion of products to other jurisdictions;
- Allowing Licensees to set their own prices and sell API (royalty-free) to each other;
- Commitments to transfer from Gilead to the licensees the technology and know-how necessary to manufacture the products;
- Quality standards: Licensees agree to seek WHO Prequalification, EMA or Tentative FDA approval;
- Active engagement with LMIC governments and NGOs to articulate the elements of the VLs;<sup>23</sup>
- Implementation of an “awareness and advocacy” campaign in targeted LMICs; and
- Transparency (the terms of all of the licenses were made public).

After 2010, the formation of the Medicines Patent Pool (described in more detail below) enabled Gilead to add another feature to its approach. In addition to concluding bilateral VLs with individual generic licensees, the company began to issue licenses to the MPP, which then issued sublicenses to generics.

In combination with the infusion of funds from donor governments, Gilead’s licensing strategy proved highly successful. The prices of its HIV drugs in LMICs dropped from \$17/month for the no-profit pricing of Gilead’s branded medicine to \$4/month for the licensed generic product. As this price dropped due to the competition among licensees, the number of people treated globally with Gilead-developed HIV medicines increased from tens of thousands in the mid-2000s to 10 million in 2016, and that number has continued to grow. As Figure 4 shows, over time a growing percentage of those drugs consisted of generic products produced pursuant to voluntary licenses, rather than Gilead-manufactured branded products.

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<sup>23</sup> Programs implemented by Gilead included studies of disease burden across the various geographies, support for medical education and training, and help to secure diagnostic capabilities.

## Access to Gilead HIV Medicines

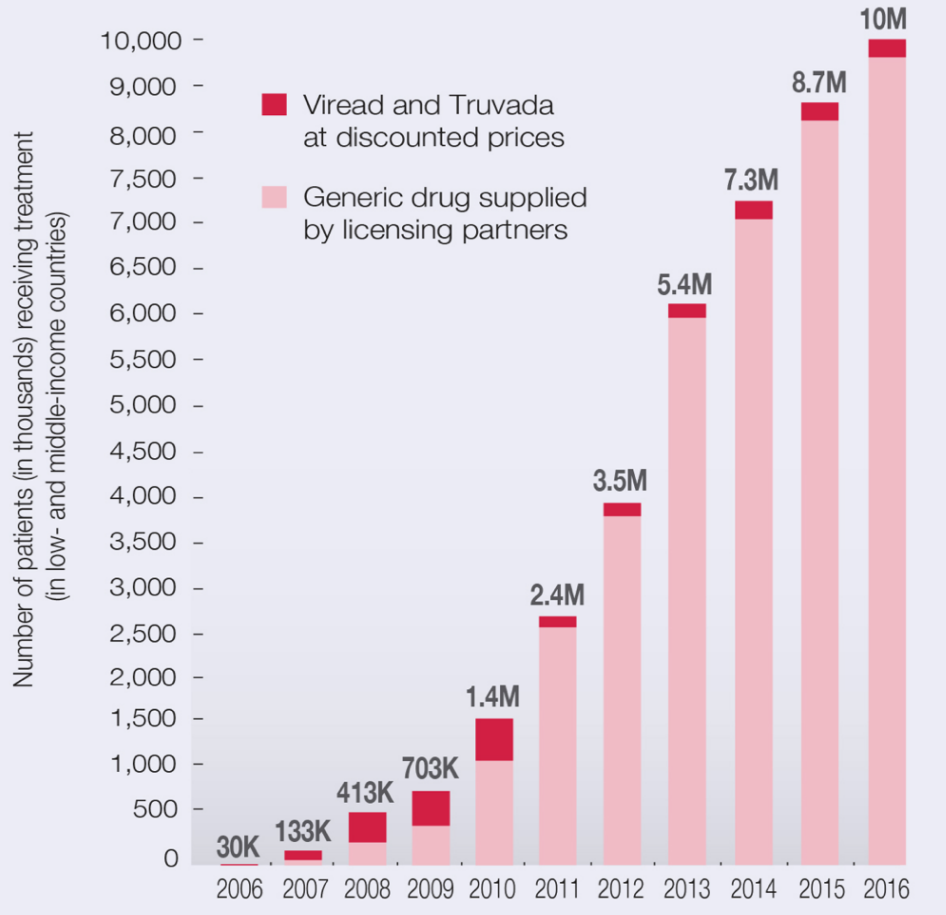


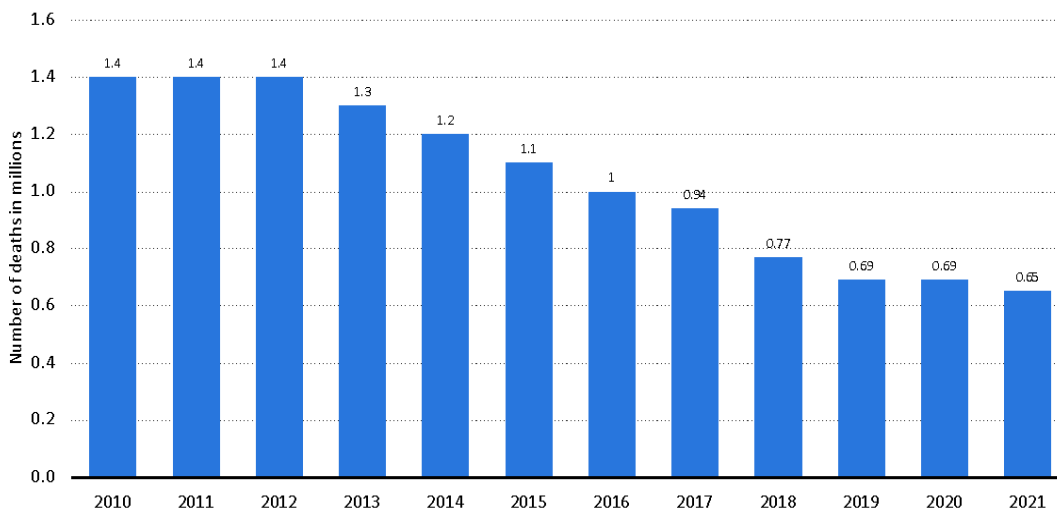
Figure 4<sup>24</sup>

Two factors seem to have been especially important in the success of the VL strategy. First, the generic companies to which the licenses were issued proved capable of manufacturing the ARVs more cheaply than Gilead. Second, the Global Fund and PEPFAR radically increased procurement of first-line ARVs in the effort to pursue their “90/90/90 Treatment for All” campaign.

To be sure, Gilead was not the only actor in the campaign against HIV/AIDS. As indicated above, the success of that campaign depended heavily on the massive infusion of funds from donor countries. In addition, other pharmaceutical firms-initiated access-oriented policies. Finally, as patents on the early ARVs expired, some firms produced and sold generic versions of them without licenses. However, Gilead’s role in the campaign was critical. For the past 20 years, the majority of ARVs distributed in LMICs have consisted of Gilead-based products. For example, in 2017, the total number of people living with HIV who received ARV treatment globally was 20.9

<sup>24</sup>Source: <https://www.gilead.com/-/media/files/pdfs/other/hiv%20access%20backgrounder%20us%20112816.pdf>.

million.<sup>25</sup> Over half of them (11.5 million) received Gilead-based treatments in LMICs, and 98% of those treatments consisted of licensed generics.<sup>26</sup> It thus seems fair to conclude that Gilead’s pioneering voluntary-licensing policy played a major role in the ongoing reduction (shown in Figure 5, below) of the global death rate from HIV.<sup>27</sup>



Source(s): UNAIDS; ID 257209



Figure 5: Total number of AIDS-related deaths worldwide from 2010 to 2021 (in millions)

## 2. Hepatitis C

Like HIV, the Hepatitis C virus (HCV) afflicts individuals in all countries, but bears most heavily on those in LMICs.<sup>28</sup> Roughly twice as many people are currently infected with Hepatitis C as are infected with HIV. As of the early 2010’s, there existed neither a vaccine nor a cure for HCV – and the standard regimen for managing the disease (a combination of pegylated interferon and ribavirin) was highly imperfect and had serious side effects. Each year, roughly 1.75 million

<sup>25</sup> UNAIDS, "UNAIDS Announces Nearly 21 Million People Living with HIV Now on Treatment," news release, November 20, 2017, 2017, [https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2017/november/20171121\\_righttohealth\\_report](https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2017/november/20171121_righttohealth_report).

<sup>26</sup> Gilead Sciences, "Impact Report: Access Operations and Emerging Markets," (2017), 4.

<sup>27</sup> UNAIDS estimates that, between 2001 and 2021, “[t]he global roll-out of HIV treatment [prevented] .... an estimated 16.5 million AIDS-related deaths.” [https://www.unaids.org/en/resources/presscentre/featurestories/2021/september/20210906\\_global-roll-out-hiv-treatment](https://www.unaids.org/en/resources/presscentre/featurestories/2021/september/20210906_global-roll-out-hiv-treatment).

<sup>28</sup> See, e.g., D. Lavanchy, "Evolving Epidemiology of Hepatitis C Virus," *Clinical Microbiology and Infection* 17, no. 2 (2011).

people were newly infected, and roughly 400,000 people died as a direct result of the disease (typically of either cirrhosis or liver cancer).<sup>29</sup>

In 2013, Gilead received FDA approval for a drug that radically changed the treatment landscape. Sofosbuvir (brand name Sovaldi), when combined with other drugs, effectively introduced a cure for HCV.<sup>30</sup> Combined with public-health measures aimed at preventing transmission of the virus, the drug created a realistic possibility of eliminating the disease altogether.

Gilead initially marketed Sovaldi in the United States at \$84,000 for a full course of treatment. Soon thereafter, the company introduced an improved version of the drug (a single pill combination treatment, which it branded Harvoni) at an even higher price. Although perhaps justified by the huge health benefits of the drugs, those prices were highly controversial. Had Sovaldi and Harvoni been marketed at similar prices in LMICs, they would have been unaffordable for all but a tiny percentage of the population. Accordingly, as soon as the FDA approved Sofosbuvir, Gilead Sciences, under the leadership of CEO Martin, launched voluntary-licensing for its HCV drugs modeled on its approach with respect to HIV drugs. Generic firms were authorized to manufacture the drugs and sell them in a large set of LMICs (which Gilead defined similarly broadly). The suite of drugs subject to the VLs eventually also included two further single-pill combination treatments (both of which provided complete cures for the disease), called Eplclusa and Vosevi.

Though Gilead's HCV access program had a dramatic impact on the disease burden in a number of countries, the outcomes of the VL program were less impactful than the HIV program on which it was based. This was principally for two reasons. First, as of 2013, fewer people (and fewer officials in LMIC public-health departments) were fully aware of the hazards associated with HCV than were aware of the dangers posed by HIV. Second, the surge in donor funding that had facilitated mass distribution of ARVs was lacking with respect to hepatitis - and no global campaign was launched analogous to the campaign addressing HIV/AIDS. The remit of the organizations leading the response to HIV/AIDS, TB and Malaria, was not expanded to include HCV. In response, Gilead commissioned studies that helped to bring to light the significant disease burden in key LMICs and demonstrated that LMIC government treatment programs would be highly cost effective in the long run. Such advocacy was very successful in Egypt (the country where the prevalence of the disease was highest) and Mongolia (which also had comparatively high HCV prevalence). Ultimately, in the absence of a global campaign and donor resources, uptake was dependent on political will and budgetary resources on a country-by-country basis.

The access program also had some side effects. On rare occasions, generic versions intended for sale in low-income countries were diverted to high-income countries. But, these instances were quickly addressed and had a minimal impact on Gilead's commercial markets in

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<sup>29</sup> See WHO, "Global Hepatitis Report," (Geneva 2017), 12, 16. (Data for 2015).

<sup>30</sup> Another, similar direct-acting antiviral drug (Simeprevir) developed by Johnson & Johnson was approved around the same time, but had more side effects and adverse drug interactions. As a result, for a substantial period, Sovaldi was the drug of choice for most patients.

the latter.<sup>31</sup> Additionally, awareness of consumers in upper-income countries of the existence of multiple versions of the drugs on the global market seems to have increased opportunities for unscrupulous distributors to sell them outright counterfeits.<sup>32</sup>

The aggregate impact of Gilead's HCV access program (even when supplemented by similar direct-acting antivirals introduced subsequently by other pharmaceutical firms) has been mixed. On the plus side, between 2015 and the present, Egypt has come close to eradicating the disease. However, over the same period, the total number of viraemic-HCV infected people in the world as a whole diminished only modestly.<sup>33</sup>

More detail concerning the trajectories of HCV in the countries that, as of 2015, bore the greatest burdens can be gleaned from Figure 6. As can be seen, among the LMICs on this list, the gains, during this critical five-year period, were greatest in Egypt (diminution in viraemic prevalence from 3.3% to 0.5%), Pakistan (3.6% to 3.3%), and India (0.5% to 0.4%). In all of the other LMICs, the percentages of infected persons who were treated and cured was small.

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<sup>31</sup> See Wolter de Vries, "Counterfeit Harvoni® Entered German Supply Chain," news release, 2017.

<sup>32</sup> See Eric Palmer, "Counterfeit Harvoni Turns up in Switzerland, Israel," *Fierce Pharma* (2016); Zachary Brennan, "Counterfeit Versions of Gilead's Blockbuster Hepatitis C Drug Found in Israel," *Regulatory Focus* (2016); "Couple Held over Bogus Hepatitis C Drug Served Fresh Warrant over Fake Harvoni Tablets," *Japan Times*, February 8, 2018.; WHO, "Medical Product Alert N°7/2020: Falsified Harvoni (Ledipasvir/Sofosbuvir)," (2020).

<sup>33</sup> See Polaris Observatory, "Global Change in Hepatitis C Virus Prevalence and Cascade of Care between 2015 and 2020: A Modelling Study," *The Lancet Gastroenterol Hepatol* 2022, no. 7 (2022): 405. The numbers reported by the World Health Organization are higher at both ends of the interval. The WHO estimated that, in 2015, 71 million people were living with chronic HCV, while in 2022, the number was 58 million. Compare WHO, "Global Hepatitis Report, 2017," pp. viii, 7, with WHO, Hepatitis C Fact Sheet (June 24, 2022), <https://www.who.int/news-room/fact-sheets/detail/hepatitis-c>.



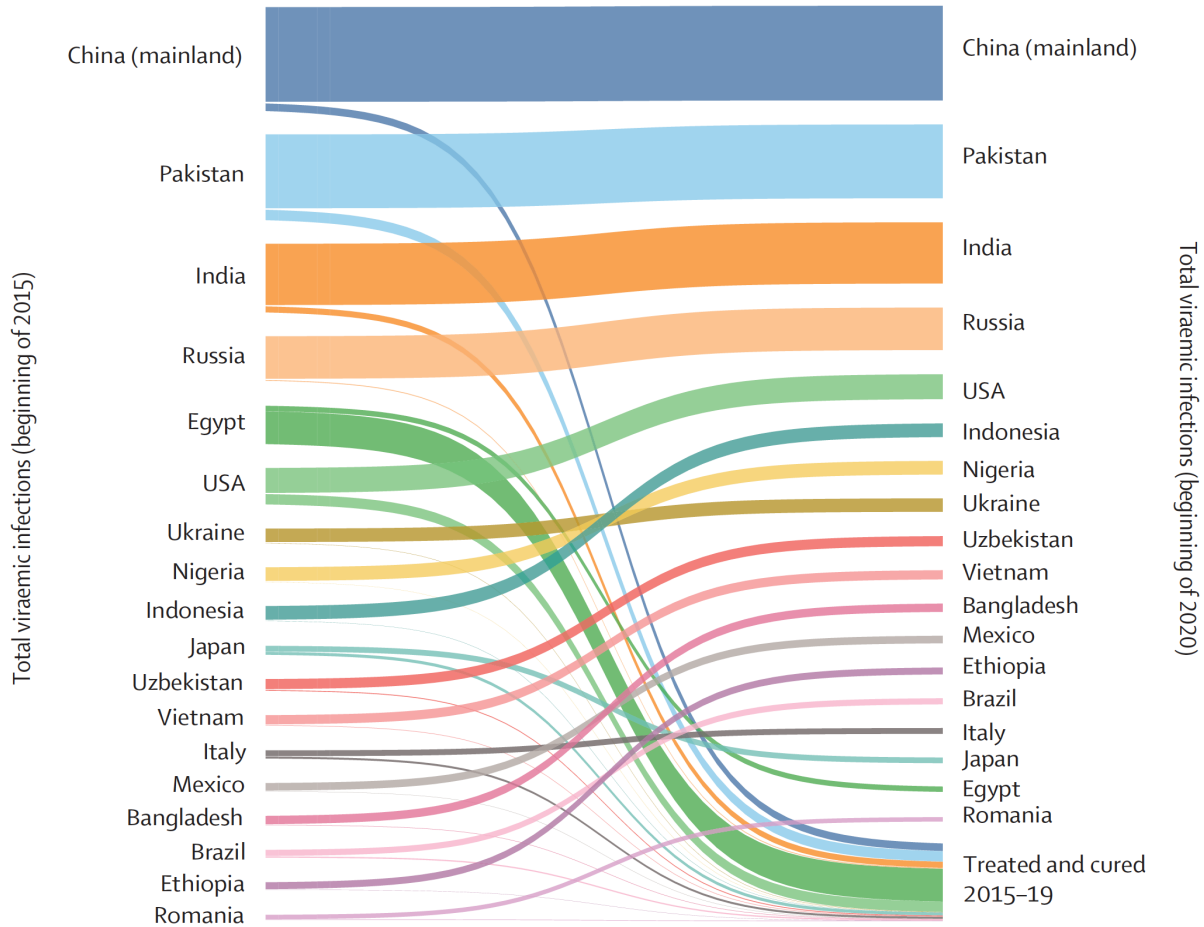


Figure 6: Sankey diagram of viraemic HCV infections in 2020, compared with viraemic infections at the beginning of 2015, including the fraction attributable to treatment and cure, among countries accounting for more than 70% of viraemic infections in 2015. Bar width is proportional to the size of the viraemic population.<sup>34</sup>

In sum, the enormous number of lives saved in a few poor countries confirm the potential power of the VL strategy. However, the disappointing results in other LMICs show some of the difficulties in successfully implementing the approach, particularly in the absence of complementary efforts (e.g., donor and LMIC government funding and programs). Making the drug available at a low price may be insufficient to ensure impact.

### 3. COVID-19

Remdesivir is a nucleotide analogue prodrug that interferes with the replication of viruses. It was originally developed by Gilead as part of a collaboration with the U.S. Centers for Disease

<sup>34</sup> Source: Polaris Observatory, supra note 33.

Control and Prevention and the U.S. Army Medical Research Institute of Infectious Diseases, which strove to identify drugs capable of curbing pandemics, such as Ebola, MERS, and SARS.<sup>35</sup>

Soon after the COVID-19 pandemic began, clinical trials suggested that remdesivir could help suppress the disease. In hopes of maximizing the availability of the drug throughout the world, Gilead entered into non-exclusive voluntary licensing agreements with several generic pharmaceutical manufacturers based in Egypt, India, and Pakistan: Cipla Ltd.; Dr. Reddy's Laboratories Ltd.; Eva Pharma; Ferozsons Laboratories; Hetero Labs Ltd.; Jubilant Life Sciences; Mylan; Syngene (a Biocon company); and Zydus Cadila Healthcare Ltd.. These licensees were authorized to manufacture remdesivir and to distribute their products in 127 countries. Included in this set were nearly all low-income and lower-middle income countries, as well as several upper-middle and high-income countries with significant obstacles to healthcare access. In most cases, remdesivir has been made available under emergency use authorizations issued by the individual countries.

Under the agreements, the licensees have a right to receive a technology transfer of the Gilead manufacturing process for remdesivir to enable them to scale up production more quickly. The licensees set their own prices for the generic products they produce. The licenses also specified that they were royalty-free until the World Health Organization declared the end of the Public Health Emergency of International Concern regarding COVID-19, or until either a pharmaceutical product other than remdesivir or a vaccine was approved to treat or prevent COVID-19.

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As mentioned above, Gilead Sciences executives approached VLs motivated by the desire to ensure the broadest access to its life-saving medicines for people in LMICs, regardless of their economic means. While Gilead believed that patents were important and should be pursued in countries where they were available, Gilead did not condition its VLs on the receipt of patents. Gilead executives believed that VLs could demonstrate that patents need not be a barrier to access, i.e., if a VL could significantly advance equitable access, then a patent for the compound in question would not threaten access if it were made widely available via VL. The mirror of this was also true, that the absence of a patent should not be used to impede access. Gilead demonstrated these points most thoroughly when it began voluntary licensing of Sofosbuvir for Hepatitis C in 2014, was issued a key patent in India in 2016, and doubled-down thereafter, by expanding its licensing of Sofosbuvir-based medicines to Indian manufacturers. Gilead's efforts demonstrated both that it was important for the purposes of "access" to move forward whether or not there was a patent in place in every relevant jurisdiction, and that the issuance of such patents would not stand in the way of access in the instances where Gilead executed its voluntary licensing. Gilead executives hoped that other companies would follow this lead.

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<sup>35</sup> For additional background on remdesivir and the roles that Gilead played in developing and testing it, see Richard T. Eastman et al., "Remdesivir: A Review of Its Discovery and Development Leading to Emergency Use Authorization for Treatment of Covid-19," *ACS Central Science* 6 (2020).

## B. The Medicines Patent Pool (MPP)

The Medicines Patent Pool was established in 2010 by UNITAID as a “global public health organization with a mandate to accelerate access to affordable and quality-assured treatments in developing countries through an innovative voluntary licensing . . . and patent pooling mechanism.”<sup>36</sup> The MPP negotiates licenses (including royalty rates) with innovators and then issues sub-licenses to generic licensees, facilitating the entry of pharmaceutical products into countries where innovators lack presence. The MPP employs tracking mechanisms to prevent generic versions of the originator’s drugs from being diverted to developed-country markets through an “Alliance Management System” (AMS). AMS supports the sub-licensees in their development and registration activities and monitors them to ensure that they abide by the terms of the VL the MPP negotiated with the originator. Finally, the MPP works with governments and other stakeholders to ensure the licenses result in product access on the ground.<sup>37</sup>

As of September 2021, the MPP had “secured access to life-saving medicines in 148 countries and negotiated more than 100 separate licenses for a wide range of drugs and vaccines.<sup>38</sup> Ten “Big Pharma” patent-holding originator companies had by then signed licenses with MPP along with 23 generics manufacturers located throughout the globe.”<sup>39</sup> Among the licensors with which MPP has partnered are:

- AbbVie,
- Boehringer Ingelheim,
- Bristol-Myers Squibb,
- F. Hoffmann-La Roche,
- Gilead,
- Janssen,
- Johns Hopkins University,
- MSD (Merck & Co. in the United States and Canada),
- Pfizer,
- Pharco Pharmaceuticals,
- the University of Liverpool,
- the United States National Institutes of Health,

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<sup>36</sup> Medicines Patent Pool (MPP), “Report to the WHO Expert Committee on the Selection and Use of Essential Medicines,” available at [https://cdn.who.int/media/docs/default-source/essential-medicines/2021-eml-expert-committee/late-papers/11\\_mpp-report.pdf?sfvrsn=79add055\\_3](https://cdn.who.int/media/docs/default-source/essential-medicines/2021-eml-expert-committee/late-papers/11_mpp-report.pdf?sfvrsn=79add055_3).

<sup>37</sup> See William Looney, “The Medicines Patent Pool Plots A Post-Pandemic Future: Interview With Director Charles Gore,” *In Vivo* (Sep. 20, 2021), available at <https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-plots-a-post-pandemic-future-interview-with-director-charles-gore>.

<sup>38</sup> For a list of the licenses of this sort secured by MPP, see <https://medicinespatentpool.org/progress-achievements/licences>.

<sup>39</sup> See Looney, *supra* note 37.

- ViiV Healthcare.<sup>40</sup>

The MPP's generic manufacturing/product development partners include:

- Adcock Ingram,
- Arene Lifesciences Limited,
- Aurobindo,
- BC,
- Beximco Pharma,
- Bill & Melinda Gates Medical Research Institute,
- Celltrion,
- Cipla,
- Desano,
- Emcure,
- Hetero,
- Langhua,
- Laurus Labs,
- Lupin,
- Macleods,
- Mangalam,
- Micro Labs Limited,
- Natco,
- Remington,
- Strides,
- SUN Pharma,
- TB Alliance,
- USV,
- Viatris,
- Zydus.

To date, generics manufacturers working through MPP have distributed more than 18.55 billion doses of low-cost medicines to LMICs.<sup>41</sup>

### **C. The COVID-19 Technology Access Pool**

As the COVID-19 pandemic swept the globe, the efforts of some countries to respond were severely restricted by limitations (both legal and practical) on access to the technologies underlying the vaccines, diagnostics, therapies, personal protective equipment, and medical devices necessary to curb the disease. In hopes of increasing access, in 2020 the World Health Organization and the

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<sup>40</sup> *Id.*

<sup>41</sup> See <https://medicinespatentpool.org/>.

government of Costa Rica catalyzed the creation of the COVID-19 Technology Access Pool (C-TAP). The Pool is similar to the MPP in that it solicits contributions (in the form of nonexclusive voluntary licenses) of intellectual property and know-how – and then issues sub-licenses to other companies and institutions. C-TAP’s primary difference from the MPP pertains to the scope of the licenses - all are global in their coverage. A diagram prepared by the WHO, showing how the system works, appears below in Figure 7.

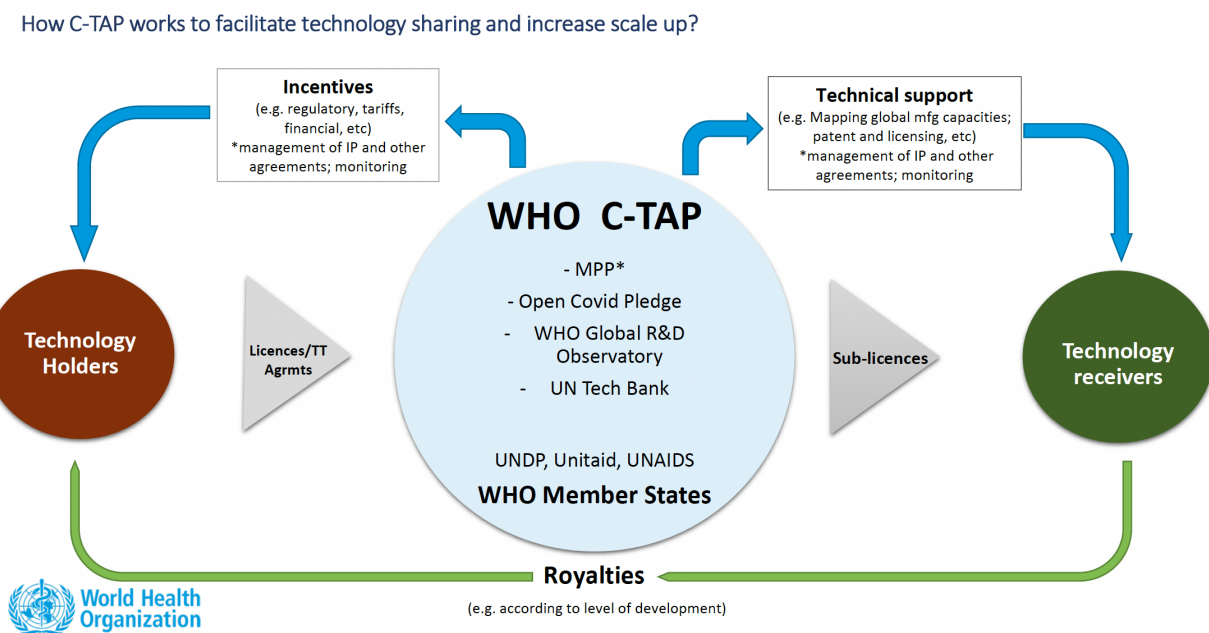


Figure 7

45 countries have endorsed C-TAP, and its partners include the UNDP, Unitaid, the UN Technology Bank, and the MPP.

Unfortunately, to-date the system has been used infrequently. Only two organizations - the Spanish National Research Council and the U.S. National Institutes of Health have issued licenses through the pool,<sup>42</sup> and only one company - Biotech Africa, has obtained a sublicense (specifically, on a COVID diagnostic test).<sup>43</sup> None of the vaccines proven effective in suppressing the virus have been licensed through the system.

<sup>42</sup> The license by the former is available at <https://www.who.int/initiatives/covid-19-technology-access-pool/csic-license>. The license by the latter is available at <https://www.who.int/initiatives/covid-19-technology-access-pool/us-nih-licenses>. The NIH’s own summary of their contributions is available at <https://www.techtransfer.nih.gov/policy/ctap>.

<sup>43</sup> “New C-TAP agreement aims to improve global access to COVID-19 testing technologies,” June 16, 2022, <https://www.who.int/news/item/16-06-2022-new-agreement-under-c-tap-aims-to-improve-global-access-to-covid-19-testing-technologies>; see [https://cdn.who.int/media/docs/default-source/medicines/c-tap/sublicence-agreement-mpp-biotech-africa.pdf?sfvrsn=59cc142e\\_1](https://cdn.who.int/media/docs/default-source/medicines/c-tap/sublicence-agreement-mpp-biotech-africa.pdf?sfvrsn=59cc142e_1).

Two factors likely contribute to this disappointing outcome. First, because C-TAP licenses are global in scope, they are not compatible with the retention of control over markets in upper-income countries. Second, at least some of the vaccines that might have been licensed through the pool involve potentially lucrative platform technologies, which the IP holders are especially reluctant to make available to other manufacturers whom they might regard as potential competitors.

## **II. Lessons**

The recent history of voluntary-licensing initiatives teaches some general lessons concerning the factors that increase or decrease their chances of success in increasing access.

### **A. Multilateral Context**

As a formal matter, a VL is typically a contract between two parties: an innovator pharmaceutical firm (the licensor) and a manufacturer of generic products (the licensee). However, if a VL in response to a public health need occurs in the absence of a broader response to that public health need by other key players, it is likely to fall short of its access-to-medicines objectives. Successful VLs are typically drafted with awareness of – and sometimes with the active participation of – several other players.

The importance of engaging multiple parties in the deployment of VLs derives in part from the complexity of the distribution chains in most LMICs. As Figure 8 shows, myriad players typically stand between the manufacturer of a drug and the patients for whom it is intended. A failure to take into account the distinct interests and competencies of these various actors is likely to impede or even prevent the delivery of the generic products to the people who need them.

**Distribution network for essential medicines in the public, private and NGO channels in developing countries**

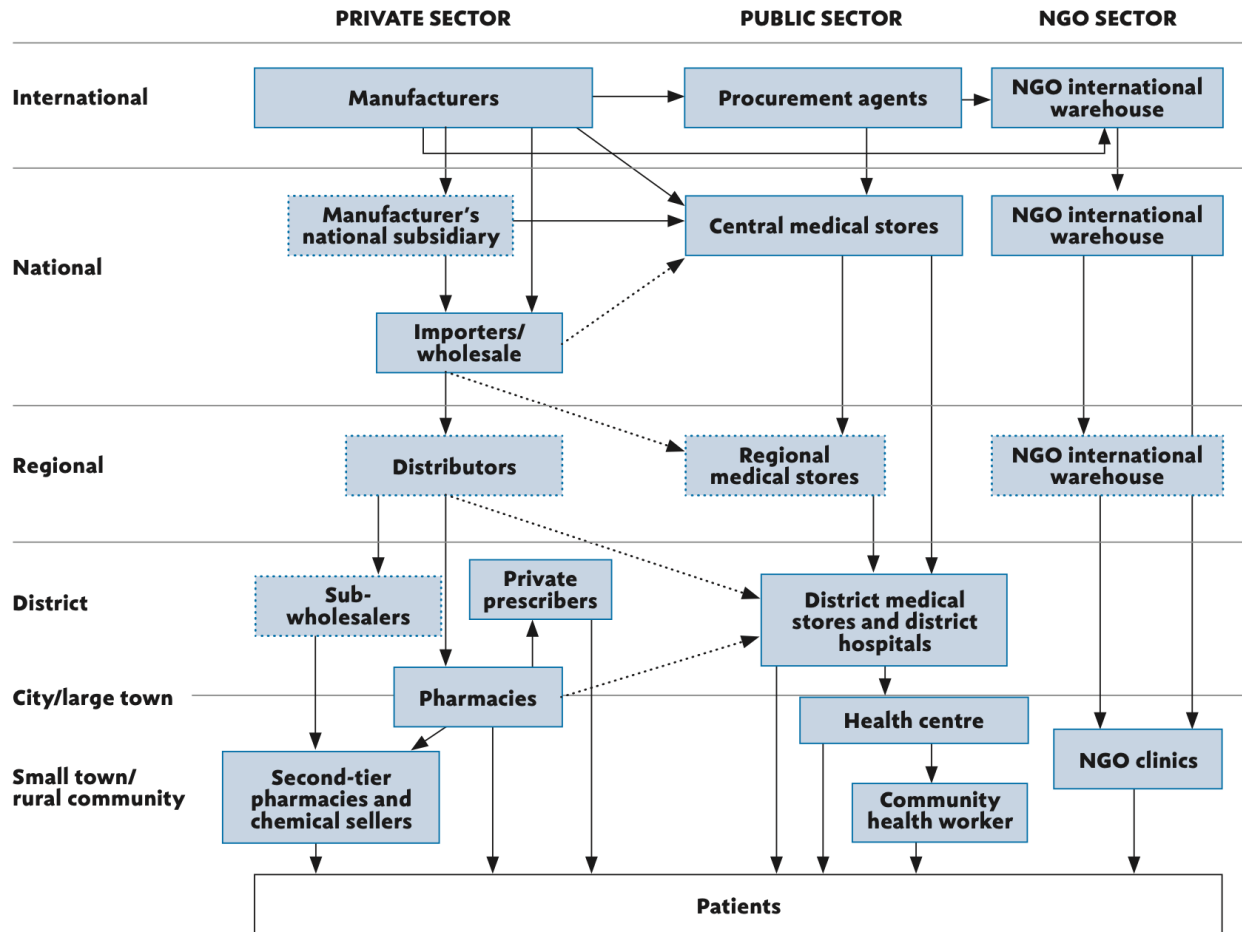


Figure 8<sup>44</sup>

In addition, several players not involved in the distribution chain itself are critical to its operation. The most important typically are:

- 1) the National Medicines Regulatory Authority [NMRA], without whose approval the product cannot be marketed at all;
- 2) donor governments or NGOs, whose financial contributions may be essential to the viability of the program; and
- 3) civil-society organizations, especially those whose principal focus is representing the patients at the end of the chains.

<sup>44</sup> Source: Pashant Yadav, Helen Lega Tata, and Magali Babaley, "The World Medicines Situation 2011: Storage and Supply Chain Management," (2011), 4.

The importance of the second set of players on this list – donors of funds that can be used to purchase and deliver the drugs produced pursuant to VLs – has become more pronounced during the past two years, as COVID-19 has decimated the health-care budgets of most LMICs. In 41 countries (most of them MICs), government spending until 2027 is projected to remain lower than before the onset of the pandemic.

Coordination and collaboration among all actors (licensor, licensee, donors, multilateral organizations, NGOs, and LMIC governments) is needed to ensure the greatest likelihood that a VL will result in significantly enhanced access to medicines. A good illustration of the benefits of multiple parties working together was Gilead’s successful engagement with the government of Egypt in the deployment of its VLs for HCV drugs there, which (as Part I.A.2. showed) depended upon close collaboration and coordination with the national government. There were several other successes - in countries where governments responded with programs to take advantage of the low-cost licensed generics available under Gilead’s VLs. Though none were on the scale of Egypt, these successes remain noteworthy.

There were many instances, however, where access goals were not achieved. Access in these cases was limited by a range of impediments, including insufficient awareness of the disease burden, lack of political will, insufficient public health funding and donor aid, failure to grant timely regulatory approval, or weak health systems.

## **B. Selectivity**

As the success of the MPP makes clear, it is sometimes feasible and desirable for a licensor to surrender control over the number and identities of the manufacturers who are authorized to produce generic versions of a product.<sup>45</sup> However, retention of such control has three potential advantages. First, it enables the licensor to provide access to its technology only to generic manufacturers that it trusts and, specifically, it is confident will adhere to quality-control standards, respect trade secrets, and work to prevent the diversion of products to upper-income countries. Second, it allows the licensor to build and maintain a set of trusted partners. These partners can serve as a cohort of future licensees, contract manufacturers, or suppliers of raw materials to the licensor. These factors all augment the incentives of each licensee to behave responsibly. This is particularly important in connection with future platform technologies. Third, retention of control enables the licensor to determine the number of manufacturers who are competing to sell generic versions of the product in each LMIC market.

The third of these advantages is not obvious. Why would the pharmaceutical firm want to limit competition? The primary objective of a VL – namely, increasing access in LMICs to affordable versions of the drug – would seem to be best advanced by maximizing competition among licensees, because it would most effectively reduce the prices of the generics in each market. Although that consideration deserves considerable weight, it is partially offset by several benefits of curbing competition enough to ensure that each licensee is able to earn a profit: it reduces the incentive of each licensee to skimp on quality control to cut costs; it increases the

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<sup>45</sup> For a description of the business strategy of the MPP, including the use of “nonexclusive licenses to encourage competition,” see <https://medicinespatentpool.org/who-we-are/business-model>.



incentive of each licensee to work actively to secure local regulatory approval for the drug as soon as possible; and it reduces the likelihood that the licensee will, to avoid financial losses, fail to produce the product under the license (which would undermine the very competition that is sought via the VL).

The strength of these factors will vary by context. In determining an appropriate number of licensees, the pharmaceutical firm should consider:

- the size of the relevant market, based upon the size of the population and the prevalence of the disease at issue;
- the likely duration of the market, which in turn will be heavily affected by whether the drug at issue is capable of eradicating the disease (like the HCV drugs) or only managing it (like the HIV drugs);
- the cost to each licensee of setting up a manufacturing line for the drug;
- the ease with which the manufacturing facility could be adapted by the licensee to other products in the future; and
- the track record of each potential licensee, which will help in predicting the likelihood that it will prove incapable of commencing or continuing production.

When building a cadre of authorized manufacturers, both licensors and licensees should be mindful of the advantages of long-term, rather than one-off, commercial relationships. Ideally, the licensor should select a set of licensees with whom it hopes to collaborate with respect to the manufacture and distribution of a series of products, rather than a single drug. Such relationships build trust and reduce transaction costs – and may reduce manufacturing costs.

Finally, the licensor should consider diversification in its distribution of licenses. Specifically, it may sometimes be optimal to enter into some licenses exclusively for the active pharmaceutical ingredient (API), so that all of the licensees producing finished goods can access API on similar terms. If one of the finished-goods manufacturers also controls the supply of the API, then that manufacturer can raise API prices to the other licensees to advantage its own finished product. Also, manufacturers that are adept at manufacturing the finished product but unable to produce the API might not enter into a VL if the API is not available through another channel. Having a diverse set of licensees, ranging from API-only producer(s), to producers capable of manufacturing both API as well as finished product, to those only making finished product, is the most optimal guarantor of broad-based access.

### **C. Quality Control**

Although substandard or falsified medical products (SFMPs), occasionally find their way into distribution chains in upper-income countries,<sup>46</sup> they are more common – and typically more

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<sup>46</sup> For examples, see Shabbir Imber Safdar, "Acting on the Drug Supply Chain Security Act," *Medicine Maker* (2022), <https://themedicinemaker.com/business-regulation/acting-on-the-drug-supply-chain-security-act.>; Jennifer Kite-Powell, "Pharmasecure Uses Mobile Device and Id Codes to Take on Counterfeit Drug Problem," *Forbes*, February 16, 2012 (documenting the discovery of counterfeit Avastin, a cancer drug, in the United States).

harmful – in LMICs. Studies have concluded that upwards of 13% of the drugs sold in LMICs are defective in some way.<sup>47</sup>

Serious consequences result when SFMPs are purchased and consumed by unsuspecting patients. Most obviously, the consumers receive either zero or reduced therapeutic or immunological benefit. As a tragic consequence, consumers in imminent peril, such as young children who have contracted malaria, are likely to die before the reason they are not recovering becomes apparent.

The long-term secondary effects of SFMPs are also harmful. In many LMICs, faith in western medicine is weak and fragile. When what appear to be legitimate drugs do no good or worse, cause harm, that limited faith further erodes. The result, of course, is to reduce the inclination of people who contract diseases to seek professional help. Equally important, the consumption of products containing less than the appropriate quantity of active ingredient contributes to the spread of drug-resistant variants of many diseases, which poses an increasingly dangerous threat to global health.

The pharmaceutical firms selling authentic versions of the drugs at issue also suffer when some of their potential sales are displaced by substandard or counterfeit products. Reputational risks also exist as LMIC consumers may develop a negative opinion of the drugs and the brands being falsely represented. Finally, in cases in which SFMPs are purchased by public-health services, the result is a waste of the countries' scarce financial resources, which in turn either drains the government's coffers or impairs their ability to address patients' needs.

One way of mitigating this risk is the common practice of including in every VL requirements for quality control, including approval by the relevant stringent regulatory authority(ies). In the case of its medicines for HIV/AIDS, Gilead Sciences required WHO Prequalification or Tentative FDA Approval. The licensor retains the right to immediately terminate the agreement if such quality control requirements are violated. Another, already mentioned means of mitigating risk of SFMPs is the issuance of VLs only to reliable, trusted manufacturers.

Although necessary, precautions of these sorts are not sufficient. SFMPs could still appear in the distribution chain for the drug at issue in one of two ways. First, properly manufactured generics can lose potency if they are stored or transported improperly. Second, when pharmacies and other dispensers experience stockouts (a common issue in LMICs), they often obtain substitutes from the black market, and some of those substitutes are counterfeit.<sup>48</sup>

To reduce these dangers, VLs should be accompanied by an effective mechanism for post-market surveillance. The ideal mechanism would be a "track-and-trace" (T&T) system of the sort

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<sup>47</sup> See Sachiko Ozawa et al., "Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries: A Systematic Review and Meta-Analysis," *JAMA Network Open* 1, no. 4 (2018); WHO, "A Study of the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products," (2017).

<sup>48</sup> See Harparkash Kaur et al., "Fake Antimalarials: Start with the Facts," *Malaria Journal* 15, no. 86 (2016): 6.

now in place in many developed countries and a few middle-income countries.<sup>49</sup> Unfortunately, the cost and complexity of a T&T regime will place it beyond the means of most LMICs for the foreseeable future. (Even in the United States, the establishment of a general T&T system will only be complete in 2023, after a decade of preparation.<sup>50</sup>)

In the absence of a global industrial solution, individual originators can look to other industries which have employed cutting-edge technologies in the fight against counterfeiting. For example, several high-end wineries have employed a tech startup, “Gliding Eagle,” to track each bottle of wine from the producer to the consumer. Utilizing a proprietary block chain methodology, RFID tags, and cloud-based capabilities, Gliding Eagle partners are able to ensure authenticity and channel accountability for their wines. In this methodology, each pallet of product and every box and each bottle within it is affixed with a unique RFID label. The labels are read by an RFID gate and the data are uploaded to the cloud at the producer site. As the pallets are shipped around the world, labels are read by scanners and these data are uploaded into the cloud. Each bottle at any point in the supply chain can be authenticated by scanning the label with a mobile phone.

Such a technology, in combination with distinct trade dress and tamper-resistant bottling, might be used by generic manufacturers to label pharmaceutical products to provide customers with an assurance of authenticity. For most generics and LMICs, however, deployment of such a system is a long way off. Until then, VLs can best meet the challenges posed by SFMPs by incorporating a surveillance system that relies, not on “tracking” all drugs from manufacturers to patients, but instead on random chemical testing of drugs at various points in the distribution chain to verify their quality. Several technologies could be employed for this purpose. None is perfect, but the current best-in-class approach uses near-infrared (NIR) scanners to compare the spectral

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<sup>49</sup> See, e.g., Joeke Kootstra and Tineke Kleinhout-Vliek, "Implementing Pharmaceutical Track-and-Trace Systems: A Realist Review," *BMJ Global Health* 6 (2021).; ICMRA, "Recommendations on Common Technical Denominators for Traceability Systems for Medicines to Allow for Interoperability," (2021).; Michael Pisa and Denise McCurdy, "Improving Global Health Supply Chains through Traceability," (Washington, D.C.: Center for Global Development, 2019).

<sup>50</sup> For a description and assessment of the emerging system, see Elona Gjini and Albert I. Wertheimer, "Review of Drug Quality and Security Act of 2013: The Drug Supply Chain Security Act (DSCSA)," *Innovations in Pharmacy* 7, no. 3 (2016).

profiles of randomly sampled drugs to the spectral profiles of authenticated drugs.<sup>51</sup> Detailed information concerning systems of this sort is available through the link in the margin.<sup>52</sup>

To function optimally, a system of this sort requires collaboration (of the sort discussed in Section II.A., above) amongst four parties:

- 1) The licensor sets the quality standards, including appropriate tolerances.
- 2) The generic licensee adheres to those standards. Equally important, each time the licensee prepares a new batch of the licensed compound, it prepares and delivers to the operator of the NIR system an authenticated spectral profile corresponding to the batch.
- 3) The operator of the NIR system then modifies the spectral library to include the new profile and updates (through the Internet) all of the portable NIR devices.
- 4) The relevant government agency in the LMIC (typically the Medicines and Poisons Board) instructs its inspectors to use the devices when taking periodic samples of the drugs in circulation.

If all four parties perform their roles, the LMIC benefits.

In the future, even better technologies for rapid, reliable testing of samples of drugs will undoubtedly appear. It would be prudent to draft a VL agreement so that the licensee is not bound to employ any particular technology, but rather is free to use the one it considers optimal. What's essential is that the agreement mandates deployment of some system of this sort.

#### **D. Local Production**<sup>53</sup>

Currently, most of the pharmaceutical products distributed and consumed in LMICs are manufactured either in upper-income countries or in large middle-income countries (primarily India, China, and Brazil). For decades, lawmakers and activists seeking to improve health conditions in LMICs have debated whether to strive to alter this situation – in other words, to increase the amounts and percentages of drugs that are manufactured locally. Advocates of

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<sup>51</sup> For descriptions and evaluations of NIR systems, see Nantasit Luangasanatip et al., "Implementation of Field Detection Devices for Antimalarial Quality Screening in Lao Pdr—a Cost-Effectiveness Analysis," *PLOS Neglected Tropical Diseases* 15, no. 9 (2021): 12-13.; P.H. Ciza et al., "Comparing the Qualitative Performances of Handheld Nir and Raman Spectrophotometers for the Detection of Falsified Pharmaceutical Products," *Talanta* 202 (2019): 477.; Wenbo Wang et al., "Evaluating Low-Cost Optical Spectrometers for the Detection of Simulated Substandard and Falsified Medicines," *Applied Spectroscopy* 74, no. 3 (2020): 332.; Stephanie Kovacs et al., "Technologies for Detecting Falsified and Substandard Drugs in Low and Middle-Income Countries," *PLoS ONE* 9, no. 3 (2014): 8, 10.; Moussa Yabré et al., "Detection of Falsified Antimalarial Sulfadoxine-Pyrimethamine and Dihydroartemisinin-Piperaquine Drugs Using a Low-Cost Handheld near-Infrared Spectrometer," *Journal of Analytical Methods in Chemistry* 2022 (2022): 6.

<sup>52</sup> See Fisher et al, *Suppressing Substandard and Falsified Drugs in LMICs* (2022), available at [https://ipxcourses.org/GPP/Fisher\\_SFMPs.pdf](https://ipxcourses.org/GPP/Fisher_SFMPs.pdf), pages 6-11.

<sup>53</sup> For a more extensive discussion of the issues addressed in this section, see William Fisher, Ruth Okediji, and Padmashree Gehl Sampath, "Fostering Production of Pharmaceutical Products in Developing Countries," *Michigan Journal of International Law* 43 (2021).

augmenting local production contend that it would benefit the residents of LMICs in two ways. First, it would create many high-paying skilled jobs and support sustainable economic development. Second, local firms could respond more quickly to the residents' changing health needs. Skeptics have responded that local production, by forfeiting economies of scale, would be less efficient and thus would raise the costs of medicines. In addition, the skeptics contend that the systems for maintaining the quality of drugs are less robust in LMICs, and thus that local production would lead to an increase in SFMPs.<sup>54</sup>

The relative strengths of these competing clusters of arguments have been altered by the behavior of national governments and pharmaceutical companies during the COVID-19 pandemic. With rare exceptions, governments, when managing scarce supplies of products capable of curbing the disease (protective equipment, diagnostics, vaccines, therapies, etc.) gave strong preference to their own citizens or residents.<sup>55</sup> Because (a) most of those products were produced in either upper-income or upper-middle-income countries and (b) the companies producing them either actively supported the governments' policies or acquiesced, the lion's shares of all the most effective products ended up in rich countries. The disparity resulted in many unnecessary deaths.<sup>56</sup>

There is no reason to suppose that either governments or companies will behave differently when they are faced with the next pandemic. Thus, if we wish not to replicate the inequity of COVID-19, we need to find ways to increase production capacity in LMICs. Pharmaceutical firms, when structuring VL programs could help advance that goal by including, within the set of licensees authorized to manufacture and sell their products, at least one generic manufacturer based in the country or region where the products are to be distributed.

An additional reason for taking this tack is that the governments of LMICs are committed increasingly strongly to augmenting local manufacturing capacity. For the reasons already discussed, a VL is far more likely to succeed if it has the active support of the local country government. Furthermore, other stakeholders in the international community are also newly focused on supporting the expansion of local production. This is another instance where increased coordination among relevant actors – e.g., donors, licensors, licensees, and LMIC governments – would help to ensure success both of the VLs and the efforts at promoting local production.

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<sup>54</sup> Compare Frederick Abbott and Jerome H. Reichman, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended Trips Provisions," *Journal of International Economic Law* 10, no. 4 (2007). with Roger Bate, "Local Pharmaceutical Production in Developing Countries: How Economic Protectionism Undermines Access to Quality Medicines," (2008); Warren Kaplan and Richard Laing, "Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines," *HNO Discussion Paper 32036* (2005).

<sup>55</sup> See, e.g., Vishnu Som, "Indian Vaccine Export Ban Makes 91 Nations Vulnerable to New Strains: WHO," NDTV, May 31, 2021, <https://www.ndtv.com/india-news/indian-vaccine-export-ban-makes-91-nations-vulnerable-to-new-strains-who-2453195>; <https://www.bloomberg.com/news/articles/2021-05-03/white-house-backs-pfizer-s-move-to-begin-u-s-vaccine-exports#xj4y7vzkg>.

<sup>56</sup> See, e.g., Sam Moore et al., "Retrospectively Modeling the Effects of Increased Global Vaccine Sharing on the Covid-19 Pandemic," *Nature Medicine* 28 (2022).

As noted above, the skeptics of local production have long contended that reliance on manufacturers located in LMICs will exacerbate the already serious problem of SFMPs. That might be true, but if so the right response is to strengthen the systems of quality control and post-market surveillance discussed in the preceding section, not to exclude local producers categorically. Many pharmaceutical manufacturers in LMICs have proved themselves to be capable of making and marketing the most sophisticated products.

Moreover, in one respect, local production is likely to reduce rather than contribute to the incidence of SFMPs. As we have noted, one of the causes of the presence in LMIC markets of bad drugs is stockouts, which prompt dispensers to turn to illicit sources in order to address their customers' demands. Drug supplies derived from local manufacturers can be delivered more rapidly to dispensers than imports and do not languish in the limbo of customs. Thus their presence in the markets should reduce the frequency or shorten the duration of stockouts, which in turn should cause fewer SFMPs to enter the distribution chains.

### **E. Technology Transfer**

Traditional “small-molecule” drugs can be reverse engineered easily by modern generic manufacturers, and thus it may not be essential for VLs pertaining to those drugs to be accompanied by agreements to make proprietary know-how available to the licensees. This is not true, however, of drugs founded upon more complex technologies, such as biologics and mRNA. Even when it is possible for generics to reverse engineer such products, forcing them to do so is highly inefficient. These new therapeutic options will be delivered to the populations of LMICs faster and less expensively if a licensor includes in a VL a commitment to transfer relevant technology and know-how to the licensees.

To be sure, the trade secrets associated with these complex new drugs are often extremely valuable, and pharmaceutical firms understandably fear that making them available to licensees could cause them to escape “into the wild.” But refusing to transfer technology is an unnecessary and ultimately ineffective way of avoiding that hazard. Instead, licensors can and should employ some of the protective strategies already mentioned – such as issuing licenses only to trusted partners and then giving those licensees incentives to be scrupulous in preventing breaches of confidentiality.

Benefits are also generated by transfers of technology in the opposite direction. Generic companies operating under VLs often develop cheaper or more reliable ways of manufacturing the drugs at issue than were known to the innovators. In addition, they sometimes develop new products based on the IP or know-how transferred. “Grant-back” provisions in VLs require the licensees to reveal and license such discoveries to the innovator at no cost and with the right to manufacture and sell those improvements.

To maximize each licensee's incentive to develop such improvements, the grant-back provisions may include a promise by the licensor not to provide the technology at issue to other licensees without permission. To be sure, such a promise may forfeit some amount of manufacturing efficiency – if the licensee responsible for a refinement refuses to license it to other members of the cadre of licensees. But a promise of this sort has the merit of accelerating the

development of improvements and of more closely aligning the interests of each licensee with those of the licensor.

## F. Maximizing Impact

A VL will achieve its intended effect of maximizing the availability of the drug at issue only if the price paid by patients is low enough to improve access materially. In a typical VL, two players have an incentive to keep prices low: the licensor and the governments covered by the license. Unfortunately, other players – most notably, the licensees, distributors, and retailers – may be more interested in maximizing their profits. Keeping their margins within reasonable bounds is crucial.

One familiar way of doing so would be for affected governments to regulate the price of the drug, either by capping the amount that may be charged at the retail level or by limiting the markups that may be made at each stage in the distribution chain. Many LMICs already maintain lists of drugs whose prices are controlled in one of these ways.<sup>57</sup> These governments could readily add to their lists drugs that enter the market through VLs.

In practice, this strategy has proven to have several disadvantages. Most are rooted in the difficulty of acquiring the information necessary to set the price of each drug at the right level – high enough to enable all essential participants in the distribution chain to earn a normal profit, but no higher. When regulators, relying on imperfect (or deliberately distorted) data, err on the low side, the result is a shortage of the drug at issue or an increase in low-quality drugs, either of which disadvantages potential consumers. When they err on the high side, the price ceiling ironically may function as a convenient target for the licensees or distributors (a phenomenon known as focal-point pricing), resulting in a retail price that is higher than it would be in an unregulated market.<sup>58</sup>

A more reliable way of curbing excessive prices is to structure a VL to harness competition. One technique has already been mentioned – ensuring that a sufficient number of licensees are operating in each country covered by the VL such that the competition drives the prices down, even as every licensee is able to earn a reasonable profit.

Another less obvious technique is for the licensor to maintain a presence in the market by continuing to offer a branded version of a particular drug. By setting the price of the branded version in LMICs at a no-profit level or at one much lower than the price in wealthier countries,

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<sup>57</sup> See WHO, "Guideline on Country Pharmaceutical Pricing Policies."

<sup>58</sup> For documentation of these disadvantages of pharmaceutical price regulation, see Iain M Cockburn, Jean O Lanjouw, and Mark Schankerman, "Patents and the Global Diffusion of New Drugs," *American Economic Review* 106, no. 1 (2016); Emma Boswell Dean, "Who Benefits from Pharmaceutical Price Controls? Evidence from India," (Center for Global Development, 2019). For an eye-opening demonstration of the hazard of focal-point pricing provoked by pharmaceutical price regulation, see Jun Li and Di Wu, "The Price Effect of Drug Price Ceilings: Intended and Unintended Consequences," (2021). The latter relies upon a data set fortuitously generated by China's sudden abandonment of drug price regulation to confirm the danger originally highlighted by Thomas Schelling, *The Strategy of Conflict* (1960).

the licensor can create a *de facto* ceiling price for the generics; no licensee will set the price of its generic at a higher level, because customers will prefer the branded version. The licensor, unlike government regulators, can adjust the cap easily as production costs shift.

This approach helped Gilead Sciences to drive down the price of generic ARVs and HCV medicines in LMICs, particularly in countries where only one or two generics were competing. By contrast, the absence of a branded version of Otsuka's product Deltyba (generic name Delamanid - a powerful drug for drug-resistant tuberculosis) in South Africa enabled Mylan, the exclusive licensee, to charge high prices (US \$640 for a six-month course of treatment), thereby sharply limiting access to the drug.<sup>59</sup>

### G. Regulatory Approval

Neither the branded version of the drug nor the generic versions authorized by the VL can be marketed in an LMIC without the approval of either the relevant NMRA or a regional regulatory authority. The following measures work well in minimizing the delays that are often associated with the regulatory processes in LMICs, particularly if pursued in combination:<sup>60</sup>

- (1) As soon as possible after receiving approval from the FDA, EMA or other SRA, the Licensor applies for marketing approval for the branded version of the drug in all of the LMICs that the VL will cover.
- (2) The Licensor waives its data-exclusivity rights with respect to the Licensees – i.e., authorizes the Licensees to use the data from the clinical trials for the branded version when seeking marketing approval for their generics.
- (3) The relevant LMIC NMRAs agree to process the applications for the branded version at least as quickly as the application for the generic versions, thereby giving no preference to the local manufacturer's generic over the originator's drug.

Two key functions of the third measure are: (a) to enable the Licensor to employ the price-containment strategy discussed in the previous section – namely, using a low price for the branded version to create a ceiling for the generics; and (b) to incentivize innovators to enter into VLs in the first place by providing them with the opportunity to earn revenues and profits from the sale of their branded product in these same LMICs. An innovator, therefore, would in such cases be

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<sup>59</sup> See MSF, "DR-TB Drugs Under the Microscope" (6<sup>th</sup> ed. 2019), p. 6, available at [https://endtb.org/sites/default/files/2019-11/MSF\\_Brief\\_DR-TB\\_Drugs\\_UTM\\_2019.pdf](https://endtb.org/sites/default/files/2019-11/MSF_Brief_DR-TB_Drugs_UTM_2019.pdf).

<sup>60</sup> For documentation of the power of these measures, see Live Storehagen Dansie, Walter Denis Odoch, and Christine Årdal, "Industrial Perceptions of Medicines Regulatory Harmonization in the East African Community," *PLoS ONE* 14, no. 6 (2019); Abigail A. Ekeigwe, "Drug Manufacturing and Access to Medicines: The West African Story," *AAPS Open Access* 5, no. 3 (2019), <https://link.springer.com/article/10.1186/s41120-019-0032-x>; Stefanie Haas, "The Who Collaborative Registration Procedure for Medicines in Developing Countries" (Rheinischen Friedrich-Wilhelms-Universität Bonn, 2015); Bakani Mark Ncube, Admire Dube, and Kim Ward, "Establishment of the African Medicines Agency: Progress, Challenges and Regulatory Readiness," *Journal of Pharmaceutical Policy and Practice* 14 (2021); Margareth Ndomondo-Sigonda et al., "Medicines Regulation in Africa: Current State and Opportunities," *Pharm Med* 31 (2017).



able to use its branded product to both set a ceiling price under which the generics' prices would fall and earn profits.

In our experience, on occasion, LMIC NMRA's have approved a licensed generic product(s) prior to approving the branded product, notwithstanding the fact that the licensee's dossier was based on the innovator's data. In some instances, the brand never got approved even when the licensee product(s) was approved. Accordingly, in order to generate the goodwill that can incentivize innovators to deploy VLs, NMRA's should prioritize the approval of the branded version when the innovator enters into VLs meeting certain minimum criteria (such as a partial waiver of data-exclusivity rights (as per item #2, above)).

If, as discussed in Section II.A, the Licensor actively engages an LMIC national government in conjunction with the deployment of the VL, then other mutually-beneficial arrangements may be feasible. For example, the Licensor might agree to increase the number of licensees that consist of local producers (which, as we have seen, LMIC governments typically strongly favor) if the relevant NMRA agrees to fast track the applications for marketing approval for both the branded version and the generic versions.

A potential objection to this last suggestion is that NMRA's typically are legally autonomous (for good reason) and thus other officials in the LMIC governments cannot simply direct them to accelerate evaluation of a particular drug. However, the walls between LMIC governmental departments are not watertight, and officials in each agency often appropriately take into account suggestions and requests from officials in others. A better alternative would be for LMIC governments to update their regulations to enable accelerated review and approval for branded and generic versions of new drugs brought to the country under a VL that meets certain minimum conditions to achieve access. LMIC governments taking such action would incentivize companies to deploy VLs, because those companies would be assured ahead of time that their branded products would have access to the marketplace in parallel with the licensed generic products.

## **H. Intellectual Property**

In a minority of the countries encompassed by Gilead's VLs for tenofovir, sofosbuvir, and remdesivir, those drugs currently enjoy patent protection. In most of those countries, however, they do not. In both groups, the licenses are working well. From this, we can infer that the availability of patent protection is neither essential to – nor an impediment to – issuance of a VL.

Mindful of the pattern just described, a pharmaceutical firm has no need to insist that a particular country issue a patent on a particular drug as a precondition for including that country in the ambit of a VL. While a firm might wish to do so as a means of extending the coverage of its suite of patents, we believe that conditioning a VL on the issuance of patents would be inconsistent with the central purpose of VLs – namely, increasing access in LMICs to affordable versions of necessary medicines. First, patent protection is not available for any pharmaceutical products in most least-developed countries or in most of the countries that are not (yet) members of the World Trade Organization. Thus, a general policy of conditioning VLs on patent protection would exclude from their coverage many of the countries most in need of improved access. Next,

obtaining patent protection is time-consuming, so making patent protection a precondition of a VL would likely delay access to the drug at issue. Finally, such conditioning of a VL on the issuance of a patent would undermine the sense of goodwill conveyed to LMIC government leaders and thereby decrease their willingness to assist in arranging and deploying it.

Furthermore, licensors may seek and obtain other forms of intellectual property protection for medicines covered by VLs. For example, in countries with laws providing for data-exclusivity protection, a licensor can use such protection to good effect. By waiving its data-exclusivity rights with respect to the licensees – but not for other generic manufacturers – the licensor can protect the licensees against unauthorized competitors and enable them to earn a normal profit without cutting corners.

Trademark protection is potentially even more useful. By enabling a licensor to prevent unauthorized uses of the name, symbols, packaging, and (in some instances) pill color that it employs to market the drug, trademarks can hobble unauthorized competitors. The processes for reviewing trademark applications are faster (and far less expensive) than the processes associated with patent applications. Trademark law is more favorably regarded, moreover, by most LMIC leaders than patent law. Finally, sensibly designed trademarks and trade dress provide consumers with useful information in differentiating authorized from unauthorized products.

Against this backdrop, a VL licensor should apply for trademark protection in every jurisdiction in the projected field of use as early as possible. That would enable the licensor subsequently to shield its branded version against imitators. In addition, the licensor should consider developing a different label and pill color to designate licensed generics. Diligent enforcement of those rights would enable the licensors and licensees to suppress any confusingly similar unauthorized generics. That would both protect the licensees' market shares and shield the reputations of licensors and licensees.

To be sure, trademark protection would not prevent entry into the market of an unauthorized generic that does not suggest to consumers that it has received the endorsement of the innovator. But, in combination, the presence in the market of reasonably priced branded products and licensed generics, the barrier created by data exclusivity, and the reputational disadvantage of lack of endorsement by the innovator should keep such intrusions to a manageable minimum.

## **I. Transparency**

Pharmaceutical firms are often reluctant to make public the terms of the contracts through which they market their products in upper-income countries. Among the reasons for their reluctance are the disadvantages of exposing the presence of rebates and the unpopularity of some of their pricing strategies.

None of these considerations is relevant to the kind of VLs with which this report is concerned, while, publicizing the terms of a VL has a major social-welfare benefit: it encourages other pharmaceutical firms to adopt similar strategies in LMICs.

Sensitivity to these considerations helps explain why almost all of the VLs discussed in Part II that have been deployed to date by Gilead, the MPP, and C-Tap are public. To our knowledge, none of the licensors has had any cause to regret this transparency.

The lesson seems clear: the terms of all VLs should be made available to the public at large.

## A Checklist for Voluntary Licensing

Atul Gawande has argued persuasively that, by making and using checklists, persons confronted by complex tasks can avoid many mistakes.<sup>61</sup> Designing and implementing a voluntary license may not be as time-sensitive or as prone to error as surgery or flying an airplane, but it can benefit from the same approach. Here is a list of issues that confront a VL, along with recommendations concerning the best approach to address each.

### 1. Purpose

**Custom:** VLs routinely state that their purpose is to increase access to certain APIs and products to satisfy unmet medical needs in the covered territory. They require conduct (price, non-diversion, marketing) consistent with that objective.<sup>62</sup> Some VLs also prohibit the licensees from engaging in any activity inconsistent with the purpose of increasing access.<sup>63</sup>

**Recommendation:** All VLs should make their access-enhancing purpose explicit. In addition, VLs should provide for the case wherein if any of their provisions are subsequently deemed ambiguous, they should be interpreted in a fashion that would promote that objective.<sup>64</sup>

### 2. Parties

**Custom:** The Licensor is invariably the owner of the IP and knowhow rights that are transferred. The Licensee is typically either a pharma company or the MPP (which is authorized to license the rights conveyed to sub-licensees on the terms specified). In addition, successful VLs require attention to be paid to the interests of other

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<sup>61</sup> Atul Gawande, *The Checklist Manifesto: How to Get Things Right* (2010).

<sup>62</sup> E.g., this agreement is intended to increase "access to quality, safe, efficacious and affordable medications...". Merck-MPP License 2021. The "Whereas" clauses of the Gilead Hepatitis C (HCV) License state that Licensor and Licensee wish "to facilitate access".

Note: All MPP licenses are available on their website. See <https://medicinespatentpool.org/progress-achievements/licences>

<sup>63</sup> MPP's MSD sublicense allows MPP to terminate after notice and a cure period if it concludes its sublicensee is failing to promote access. Para. 10.4.

<sup>64</sup> This recommendation reflects Karl Llewellyn's insight that the "rightest and most beautiful type of legal rule, is the singing rule with purpose and with reason clear." Only rules of that sort, he argued, were capable of providing effective guidance to judges, lawyers, and "the interested layman, . . . the law-consumer, . . . the law-supporter, . . . the man whose law our law is."

stakeholders, including LMIC governments, funders, multilateral organizations, civil-society organizations, and distributors.

**Recommendation:** Licensor and licensee should agree to cooperate in encouraging such other stakeholders to partner in helping to improve health care infrastructure in the territory covered by the license.

### 3. Rights Transferred

**Custom:** Typically, the Licensor conveys the right to use specific IP or knowhow to manufacture and/or sell specified products and related APIs in particular territories. The countries covered and the status of the patents involved are often listed in appendices.<sup>65</sup> Typically, the license is non-exclusive, non-sublicensable (or with limited sublicensing rights requiring notice to Licensor, audits, and assumption of liability) and non-transferrable (except to affiliates).<sup>66</sup> Transfers of specified products are sometimes preconditioned on FDA approval. Licenses to the MPP convey the right to sublicense the rights transferred and to sell outside the licensed territory for authorized uses including sales by public authorities.<sup>67</sup> Sales through third parties are controlled to ensure Licensor approval of the parties and compliance by them of all terms of the license. The transfer may be deemed “one time.”

**Recommendation:** A VL should include assurances by the Licensor to provide useful knowhow to Licensees, including training where necessary. Licensees should be empowered to sell into additional territories upon establishing the need for increased access in such areas and Licensee’s capacity to perform.

### 4. Quality Standards

**Custom:** In a VL, Licensees are free to source API from any authorized source they choose, and to sell API royalty-free to each other. That API is then used by the licensee to manufacture the finished product. Gilead required Licensees to obtain WHO Prequalification and/or Tentative FDA Approval to ensure acceptable quality standards are met. However, this is not necessarily an industry standard practice for producers of generic medicines.

**Recommendation:** In order to ensure quality standards, Licensees should be required to seek approval via a stringent regulatory authority (e.g., WHO Prequalification, Tentative FDA approval if applicable, or European Medical Agency (EMA)).

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<sup>65</sup> See Gilead HCV License, App. 1&2.

<sup>66</sup> See Gilead HCV License, Para. 3.4.

<sup>67</sup> MPP MSD License, Para. 2.3. (All MPP licenses are available on their website. See <https://medicinespatentpool.org/progress-achievements/licences>.)

## 5. Sales and Marketing

**Custom:** Typical provisions pertaining to the sale and marketing of products authorized by a VL include: all statements by Licensees related to products based on the license must be accurate; any reference to the Licensor on or associated with the products sold must be approved by the Licensor in writing; all products sold must indicate they are made pursuant to a license from Licensor; distinct trade names and trade dress may be required; Licensee must terminate any third-party seller that fails to abide by the terms of the license.<sup>68</sup>

**Recommendation:** The Licensor should maintain oversight of key aspects of sales and marketing behavior and the use of trademarks by Licensees, both to protect the Licensor's reputation and to protect the reputation of the licensing regime.

## 6. Compliance with Laws

**Custom:** A VL typically provides that the Licensee must comply at its own expense with all applicable laws and regulations, including the procedures for obtaining regulatory approval and all safety related reports. Licensee must also comply with bribery/corruption statutes, and Licensor is not responsible for Licensee misconduct.

**Recommendation:** Such obligations are sound but should be supplemented by a commitment by the Licensor to assist the Licensee in obtaining regulatory approvals (e.g., timely submission of product dossier to WHO for prequalification review or to an SRA).

## 7. Liability

**Custom:** The Licensee typically indemnifies the Licensor for damages caused by Licensee's performance. Licenses exclude liability of Licensor for any form of "Special Damages (including exemplary, punitive, loss of profits, etc.)." Licensee typically is responsible for claims by third parties based on Licensee's conduct but must get Licensor's written consent to any settlement by Licensee of such claims. Licensees may be required to obtain insurance to cover claims for products made or sold.<sup>69</sup>

**Recommendation:** Provisions of these sorts designed to ensure that the Licensee bears financial responsibility for the Licensee's misconduct are sound. In addition, a VL should specify the kinds of misconduct that will constitute grounds for terminating the License.

## 8. Termination

**Custom:** Termination is allowed by either party with a notice and cure period (e.g., 30 days) for material breaches of material terms. Licensor may be allowed to terminate

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<sup>68</sup> See, e.g., Gilead Tenofovir License, Para. 2.4(e)

<sup>69</sup> See Gilead, HIV License Para. 9 (no less than \$1 million per year).

immediately where in good faith it concludes control of the Licensee has changed or specified breaches have occurred, such as diversion, inadequate quality, using APIs from unauthorized sources, non-payment of royalties, insolvency, etc. Licensees may be given a specified period to establish that the conditions cited by Licensor do not exist. Licensor or Licensee rights under the license may be deemed to survive in specified circumstances, as where investments have been made. Licensee may be given the right to terminate its use of licensed APIs or patents after a specified period.

**Recommendation:** Provisions such as those outlined above are designed to protect the integrity of the licensing program.

## 9. Confidentiality

**Custom:** Licenses uniformly provide for the maintenance of confidentiality of all information shared on that basis. Information publicly available may not be deemed confidential, and the obligation to maintain confidentiality is inapplicable in the event a court or agency with appropriate authority concludes that the information should not be confidential.

**Recommendation:** The license should specify obligations regarding confidential information and whether confidentiality applies to any mediation and/or arbitration.

## 10. Use of Names & Agency

**Custom:** Parties of VLs typically agree not to use each other's names with such exceptions as they decide to make. The parties are deemed to be independent contractors with no authority to bind each other except by written agreement.

**Recommendation:** Licenses should include such provisions as they enable parties to protect their interests with minimum reliance on IP rights and litigation.

## 11. Dispute Resolution

**Custom:** VLs typically specify the jurisdiction whose laws will govern any dispute between Licensor and Licensee. Most VLs provide for arbitration of all disputes, after an effort to mediate. Some specify the terms and provider of arbitration services (e.g., number of arbitrators, applicable rules, deadlines). With respect to litigation, VLs sometimes specify the court that shall have jurisdiction.

**Recommendation:** A VL should provide such guidance for resolving any disputes. In addition, a VL can provide for fee shifting in general or for specific violations (e.g., in the event of unauthorized or improper use of the IP transferred).

Each of the preceding recommendations is grounded in a substantial body of custom. In other words, our guidelines draw support from a record of successful deployments of VLs. By contrast, the issues discussed below are intended to complement the actions of the private parties that negotiate a VL.

## 12. Regulatory Approval

**Analysis:** It is important to provide opportunity for the innovator to sell its branded product alongside the licensed generic products. This is especially important in the large market middle-income countries such as Egypt, India, Indonesia, and South Africa, with sizeable wealthier populations who could afford and may wish the choice of a branded product. The presence of a reasonably-priced branded product in the market can also serve to create a ceiling price, under which the generic products prices would fall.

**Recommendation:** The government of each LMIC within the field of use of a VL should agree in advance (a) to process expeditiously applications for regulatory approval and (b) to treat equally applications from Licensor and Licensees.

## 13. Health Financing and Advance Marketing Commitments

**Analysis:** Resources are required to ensure uptake of the medicines made available to patients. Funding for procurement of the medicines is required, whether from the LMIC governments or from donor agencies. Ideally, a VL would be implemented in the context of coordination between licensor, licensees and funders.

**Recommendation:** Mechanisms should be established that allow for greater coordination among donors, LMIC governments, innovators and generic manufacturers to maximize access to medicines made available via VLs. Among other things, donor agencies and the governments of each LMIC within the field of use of a VL can increase access by agreeing in advance to purchase specified quantities of the drug at agreed prices.

## 14. Post-Market Surveillance

**Analysis:** See Section II. C. above.

**Recommendation:** The governments of LMICs should institute systems for minimizing the presence in their markets of substandard or falsified versions of either the generics or the branded versions of the drug subject to a VL. If the technology used for this purpose requires maintenance of a library of spectral profiles, then both the Licensor and the Licensees should commit to maintain the relevant portion of the library by promptly supplying the appropriate enforcement authority with authenticated profiles of each batch of their products.

## 15. Intellectual Property Protection

**Analysis:** See Section II.H. above.

**Recommendation:** Licensors should not condition VLs on the presence of patent protection within the relevant countries. However, LMIC governments should extend trademark and trade-dress protection to Licensors' names, symbols, and product configurations. In addition, in jurisdictions that recognize data-exclusivity

protections, LMIC governments should provide such protection to Licensors, conditional upon the execution and implementation of appropriate VLs.

### III. Opportunities and Impediments

Voluntary licenses benefit everyone.

- The innovator pharmaceutical firms that enter into such arrangements benefit in several ways. Sales of branded versions of the drugs in combination with royalties from the licenses provide the innovators with a viable revenue stream. Furthermore, VLs also enable innovators to meet their access and ESG commitments and generate goodwill. Additionally, innovators can secure access to raw materials essential for manufacturing the product; and access to improvements made by the Licensees in either the product itself or the process by which it is manufactured.
- The generic manufacturers to which such licenses are issued obtain reliable access to local markets, which enables them to make reasonable profits without cutting corners.
- Populations of LMIC countries obtain improved access to affordable, high-quality versions of crucial drugs long before the expiration of the intellectual-property protections for the drugs.
- Finally, the public-health systems of covered LMIC countries are able to obtain major health benefits for their citizens while mitigating the impact on public-health budgets.

In short, everyone wins. Why then are so few of these VLs negotiated and implemented? Five factors seem to be at work. Part III of this Report sets forth in detail our proposals with respect to each of them. Those proposals are summarized below.

1. **Complexity.** VLs are more complicated than the kinds of licenses with which both innovators and generic manufacturers are familiar. The complexity of VLs is exacerbated by the fact that they work best when innovators and generics engage other parties – most importantly, LMIC governments and funders.

*Response:* One of the principal objectives of the checklist presented in Part III of this report is to help all parties deal with these complexities.

2. **Hazards.** The most obvious reason that executives shy away from VLs is that they are seen as a charitable mechanism that forsakes the maximization of revenues and profits. Executives of innovator companies also identify other dangers that VLs pose to their firms, including (i) diversion of low-price products from LMICs to UICs and (ii) loss of control over valuable platform technologies.

*Response:* In the checklist presented in Part III, we have identified provisions designed to address each of these legitimate concerns. Even more important than those



contractual shields is the general structure we recommend: careful selection of a modest number of trustworthy licensees combined with features that give those licensees incentives to respect the licensor's wishes regarding diversion, trade secrets, and quality.

3. **Autonomous Business Unit.** Some innovator firms are not structured to optimize their navigation of LMIC markets, including execution of VLs alongside their branded products.

*Response:* Presuming that a more conducive international environment for VLs evolves (which our recommendations are geared towards achieving), companies should adapt to implement a new strategy for LMICs. Companies should consider creating an autonomous business unit focused on doing business at the base of the economic pyramid in LMICs, combining sales of branded products with VLs.

4. **Regional Preferences.** One of the most important byproducts of the disparities in the distribution of COVID vaccines has been the increasingly strong commitment of LMIC leaders to local production of crucial drugs. "Never again," they now often say, "will we expose ourselves to the variability of the charitable impulses of the leaders of upper-income countries; we must build the capacity to produce drugs locally." Pharmaceutical executives, for their part, are often skeptical of the capacity of generic manufacturers based in developing countries to handle the complex technologies necessary to produce many modern drugs – and thus are unenthusiastic about "local production."

*Response:* Three things, in combination, make it possible to overcome this impediment to the increased use of VLs. The first is technology transfer and assistance with knowhow. With these enabling tools, the generic firms that are prospective licensees in developing countries can be brought up to speed to manufacture novel technologies. The second is the growing track record of some of the firms in LMICs. As their accomplishments become more evident in the production of newer therapies, skepticism among innovators should subside. The third is the increased commitment by donors to finance both the expansion of local production capacity and procurement of locally-produced medicines.

5. **A Climate of Suspicion and Confrontation.** Hostility among the actors whose collaboration is essential to progress in mitigating the global health crisis is distressingly common – and makes it harder to have the kinds of conversations essential to the successful outcome of VLs. If all essential parties collaborate in the negotiation and implementation of a VL, they all win. However, many actors do not see the value from the outset, and some who engage are tempted to defect. Licensees, in particular, may be reluctant to commit their resources without assurance that there will be adequate funding to procure their products. Licensors may balk at forfeiting commercial opportunities or placing at risk new platform technologies without respective assurances in each area. Civil-society organizations may stay away from the

table due to their mistrust of innovators and hostility to IP protection. Finally, representatives of LMIC governments may steer clear because they don't yet see that they have a stake in the use of VLs.

*Response:* There is no simple solution to this last problem. In our experience, the most promising of the possible responses is to convene meetings, attended by representatives of all relevant groups, and then structure those meetings to foster frank but respectful discussions of how best to pursue the common goal of achieving more equitable access to life-saving medicines. The conferences at Harvard and Stanford in the early stages of this project were designed with that in mind. Similar gatherings are likely to be necessary to realize the potential of VLs. It is vital to find mechanisms to bring all parties to the table, and a multilateral institution or NGO is likely to be the best equipped to bring these diverse actors together to facilitate and incentivize VLs as a core component of the global effort to improve public health in LMICs.

#### **IV. Conclusion**

VLs can and should be used more often as a non-coercive approach to increase access to medicines in LMICs. The collaborations that we recommend would enable and significantly improve the efficiency of a global health system that often gets mired in friction among stakeholders, raising the social and economic costs for all players and, most damagingly, for those lacking access to essential healthcare in emergency situations. With nearly 2 billion people globally without access to essential medicines, an urgent need exists for a multi-pronged international approach to improving access. Making VLs a key component of such distributive efforts can catalyze cooperation that advances global public health outcomes and benefits those in need in LMICs.

## V. Abbreviations and Acronyms

AIDS	Acquired Immunodeficiency Syndrome
API	Active Pharmaceutical Ingredient
CSR	Corporate Social Responsibility
DFC	U.S. Development Finance Corporation
EMA	European Medicines Agency
ESG	Environmental, Social and Governance
FDA	U.S. Food and Drug Administration
GDP	Gross Domestic Product
GNI	Gross National Income
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IP	Intellectual Property
IPR	Intellectual Property Rights
LDC	Least-Developed Country
LMICs	Low- and Middle-Income Countries
MOF	Ministry of Finance
MOH	Ministry of Health
MPP	Medicines Patent Pool
NCD	Non-communicable disease

NGO	Non-Governmental Organization
PEPFAR	President's Emergency Program for AIDS Relief
PhRMA	Pharmaceutical Research and Manufacturers of America
R&D	Research and Development
TRIPS	Agreement on the Trade-Related Aspects of Intellectual Property Rights
USAID	United States Agency for International Development
USD	United States Dollar
VL	Voluntary License
WHO	World Health Organization
WTO	World Trade Organization

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## VII. Conference Participants

Crucial to the creation of this report were two conferences, the first held at Harvard Law School in April of 2022, the second at Stanford Business School in September of 2022. The participants in those meetings are listed below. Many of the recommendations offered in the report have been heavily influenced by their interventions. However, it should not be assumed that any of them agree with any or all aspects of the report -- or that any of the organizations they represent endorse the report.

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