

UNMET NEED FOR PAXLOVID IN LOW- AND MIDDLE-INCOME COUNTRIES DURING COVID- 19 EMERGENCY

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October 17, 2023



ACKNOWLEDGMENTS

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INTRODUCTION

Today, the United States International Trade Commission (USITC) is releasing the results of its fact-finding investigation on access to COVID-19 diagnostics and therapeutics and flexibilities under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.¹

The United States Trade Representative called for the investigation at the end of 2022 and requested information on topics ranging from supply chain and distribution to compulsory licensing and access to medicines.² The investigation is expected to help guide the United States' consideration of an extension of the June 17, 2022 World Trade Organization Ministerial Decision on the TRIPS Agreement (the 'TRIPS Decision') to diagnostics and therapeutics.

In Public Citizen's submission to the fact-finding investigation, we looked back on the inequitable rollout of Pfizer's Paxlovid (nirmatrelvir-ritonavir) in 2022, the WHO's antiviral of choice for high-risk patients, to highlight the large gaps in access to the therapeutic that resulted in the unmet health needs of patients in low- and middle-income countries (LMICs).³

To determine the extent to which the procured supply of Paxlovid in LMICs during 2022 could adequately meet the health need of patients, we reviewed purchase agreements and procurement mechanisms that supplied LMICs with Paxlovid and compared this figure with the estimated health need among LMICs in 2022. **The health need for Paxlovid exceeded procured supply by over eight million courses in 2022, leaving 90% of health need unmet by the shortage of Paxlovid in LMICs.**

In addition to being the treatment of choice throughout the time period assessed in this analysis, the WHO's most recent guidelines strongly recommend nirmatrelvir-ritonavir for patients with non-severe COVID-19 at highest risk of hospitalization.⁴ However, the COVID-19 products that are currently on the market represent a small subset of the future tools that will be developed to combat the virus.⁵

¹ U.S. International Trade Commission, USITC TO REPORT ON COVID-19 DIAGNOSTICS AND THERAPEUTICS AND FLEXIBILITIES UNDER THE TRIPS AGREEMENT, 1 February 2023, <https://www.usitc.gov/press_room/news_release/2023/er0201_63483.htm>

² U.S. International Trade Commission, Ambassador Tai TRIPS Request Letter to USITC, 16 December 2022, <https://www.usitc.gov/research_and_analysis/786496-1929259.pdf>

³ Public Citizen, Comments to USITC: TRIPS Flexibilities for COVID-19 Diagnostics & Therapeutics, 5 May 2023, <<https://www.citizen.org/article/comments-to-usitc-trips-flexibilities-for-covid-19-diagnostics-therapeutics/>>

⁴ World Health Organization, Therapeutics and COVID-19: living guideline, 12 January 2023, <<https://app.magicapp.org/#/guideline/nBkO1E/rec/jDBZ3n>>

⁵ Biotechnology Innovation Organization, BIO COVID-19 Therapeutic Development Tracker, <<https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker>> [accessed 16 October 2023]

Looking to the future, this analysis provides a stark example suggesting that, absent further reforms, when patented pandemic-fighting tools come to market, LMICs may often be left with initially limited supply at prices much higher than they could be in a robust generics market. Suppressed demand, resulting in insufficient supply for patients, is in part a symptom of intellectual property barriers, among other challenges.

SUPPLY OF PAXLOVID FELL FAR SHORT OF HEALTH NEED IN 2022

Low- and middle-income countries secured Paxlovid in 2022⁶ through bilateral supply agreements with Pfizer, pooled procurement mechanisms, and donations. We relied on publicly available information for this analysis. Additional data from Pfizer could help complete an exhaustive account of Paxlovid supply in LMICs during 2022.

Bilateral Supply Agreements

To identify bilateral supply agreements between LMIC governments and Pfizer, we used data from the Duke Global Health Innovation Center’s Launch and Scale Speedometer (the ‘Duke Dashboard’). During the COVID-19 emergency, the Duke Dashboard tracked purchases of COVID-19 therapeutics, aiming to provide a comprehensive record of these purchases.⁷ However, this data was limited to publicly available purchase agreements, and may exclude relevant Paxlovid purchase agreements or information.

As of May 2023, the Duke Dashboard reported that 48,350,517 courses of Paxlovid had been purchased worldwide, with over 70% of the courses having been purchased directly through high-income country bilateral supply deals. Lower middle-income countries (Egypt and Ukraine) purchased a total of 320,000 courses and upper middle-income countries (Mexico, Thailand, and Malaysia) purchased a total of 460,000 courses.

Table 1: LMIC Bilateral Supply Agreements for Paxlovid (through 2022)

Purchasing Country	Courses
Mexico	300,000

⁶ It is important to note that we did not exclude purchase agreements that were completed prior to 2022. Additionally, it could be argued that purchases made in late 2022 were reflective of projected health need in 2023. As a result, this estimation of procured supply could overrepresent the true market demand for Paxlovid, when compared to health need, in 2022. Regardless, as Pfizer began negotiating purchase agreements in late 2021 and this analysis was completed in early 2023, we believe that it was a fair estimation of market demand for 2022.

⁷ Duke Global Health Innovation Center Launch and Scale Speedometer. Available at: <<https://launchandscalefaster.org/covid-19/therapeutics>> [accessed 17 February 2023].

Ukraine	300,000
Malaysia	110,000
Thailand	50,000
Egypt	20,000
Total	780,000

Source: Duke Global Health Innovation Center Launch and Scale Speedometer

Pooled Procurement Mechanisms

Two partners of the Access to COVID-19 Tools Accelerator (ACT-A) entered into agreements with Pfizer for 10 million courses of Paxlovid for LMICs (6 million Global Fund; 4 million UNICEF), which are included in the Duke Dashboard.⁸ To our best knowledge, these agreements functioned as options agreements rather than fully paid-up advanced purchase agreements. The courses available to ACT-A partners are offered to eligible countries and countries then confirm the number of courses they want to receive, at a price that is based upon the country's income status. With this model, we considered the amount procured by a country to be the number of courses that were confirmed, rather than the total amount optioned by ACT-A partners. Using the World Health Organization Therapeutics Dashboard, we determined that by the beginning of 2023, 2,132,304 courses of Paxlovid had been offered to LMICs by ACT-A, but only 135,120 courses were confirmed by 19 countries (Table 2).⁹

Table 2: Nirmatrelvir Units Confirmed Through ACT-A by LMICs

Country	Units Confirmed
Cambodia	94,320
Indonesia	24,096
Zambia	4,656
Tunisia	2,304
Belize	1,632
Philippines	1,392
Ghana	1,296
Bolivia (Plurinational State of)	1,200
Tuvalu	672
Kiribati	576
Tajikistan	528
Kenya	480

⁸ World Health Organization Therapeutics Dashboard, <<https://partnersplatform.who.int/en/therapeutics-dashboard>> [accessed May 2023]

⁹ World Health Organization Therapeutics Dashboard, <<https://partnersplatform.who.int/en/therapeutics-dashboard>> [accessed May 2023]

Lao People's Democratic Republic	480
Samoa	384
Micronesia (Federated States of)	336
Marshall Islands	240
Tonga	240
Nauru	192
Fiji	96
Total	135,120

Source: WHO Therapeutics Dashboard

The Global Fund and UNICEF agreements have been viewed as evidence of a surplus of Paxlovid supply in LMICs. Not only did these agreements come much later to LMICs, with the U.S. and other rich countries buying much of the initial supply, but, notably, less than 1.5% of the Paxlovid courses optioned by the ACT-A partners have actually been procured by countries.¹⁰ Although 10 million courses were optioned by ACT-A and 2,132,304 courses were offered to countries, the actual procured supply by the beginning of 2023 was only 135,120 courses. This stark divergence indicates not only that the alleged surplus of supply did not exist for patients in LMICs, but also that the prices offered through these options agreements were still too high to induce substantial demand. In other words, even when LMICs had the opportunity to purchase Paxlovid at the “not-for-profit” and “tiered price,” it was too expensive.

The European Commission also announced a joint procurement contract with Pfizer in late November 2022.¹¹ Thirteen countries are participating in the agreement, with the option to purchase up to nearly 3.5 million Paxlovid courses over 12 months. But details on this agreement were scant. In November 2022, a representative from the Estonian Health Insurance Fund said that “it remains very difficult to predict when the drugs might hit pharmacies.”¹² It is reasonable to assume that the vast majority of the courses were or will be procured throughout 2023, mostly by high-income countries such as Estonia, so we excluded the courses optioned through this agreement from our analysis.¹³

¹⁰ The White House, Biden Administration Increases Access to COVID-19 Treatments and Boosts Patient and Provider Awareness, 26 April 2023, <<https://www.whitehouse.gov/briefing-room/statements-releases/2022/04/26/fact-sheet-biden-administration-increases-access-to-covid-19-treatments-and-boosts-patient-and-provider-awareness/>>; Pfizer did not complete negotiations with UNICEF and Global Fund for the options contracts with Pfizer until Sept. 2022, 8 months after the start of rollout of Paxlovid in the US <<https://www.theglobalfund.org/en/news/2022/2022-09-22-the-global-fund-signs-agreement-with-pfizer-to-expand-access-to-paxlovid-antiviral/>>

¹¹ European Commission, European Health Union: Commission secures almost 3.5 million COVID-19 treatments through joint procurement contract, 23 November 2022, <https://ec.europa.eu/commission/presscorner/detail/en/IP_22_6491>

¹² ERR News, Covid drug joint tender mired, direct purchase conditions draconian, 16 November 2022, <<https://news.err.ee/1608790612/covid-drug-joint-tender-mired-direct-purchase-conditions-draconian>>

¹³ While the majority of the courses are likely to be procured throughout 2023, there may be a small number of courses that were procured by European developing countries during December 2022. Given the limited

Donations

In addition to bilateral and multilateral Paxlovid purchase agreements, it has been reported that Pfizer donated 100,000 Paxlovid courses to the COVID Treatment Quick Start Consortium, an initiative that aims to scale-up access to COVID-19 antivirals in 10 partner countries.¹⁴ Zambia was the first country to receive a shipment, with 1,000 courses arriving near the end of 2022.¹⁵

Based on the available data, we estimated that throughout 2022 LMICs ordered or requested 916,120 courses of Paxlovid (Table 3).¹⁶

Table 3: Procurement of Paxlovid by LMICs (2022)¹⁷

Purchasing Country or Entity	Courses
Mexico	300,000
Ukraine ¹⁸	300,000
ACT-A	135,120
Malaysia	110,000
Thailand	50,000
Egypt	20,000
Zambia	1,000
Total	916,120

publicly available details on this agreement, we were not able to determine which countries are part of the agreement, how many doses have been procured, and the date of the procurements.

¹⁴ Reuters, Pfizer donates Paxlovid to group targeting COVID in poorer countries, <<https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-donates-paxlovid-group-targeting-covid-poorer-countries-2022-09-07/>>

¹⁵ COVID Treatment Quick Start Consortium, Laos, Malawi, Rwanda and Zambia Have Received Oral Antiviral Treatments for High-Risk Patients Through COVID Treatment Quick Start Consortium, <<https://www.covidcollaborative.us/assets/uploads/img/16-March-2023-Press-Release-Laos-Malawi-Rwanda-and-Zambia-Have-Received-Oral-Antiviral-Treatments-for-High-Risk-Patients-Through-COVID-Treatment-Quick-Start-Consortium.pdf>>

¹⁶ It is important to note that we did not exclude purchase agreements that were completed prior to 2022. As a result, this estimation could overrepresent the true market demand, when compared to health need, in 2022. Regardless, as Pfizer began negotiating purchase agreements in late 2021, we believe that our methodology has resulted in a fair estimation.

¹⁷ The data in Table 3 is limited to the purchase agreements identified through the described methods. This may not include other purchase agreements between Pfizer and LMICs that are not publicly available.

¹⁸ Ukraine reportedly entered into a supply agreement with Pfizer for 300,000 courses in December of 2021. Pfizer has since reported that they donated 200,000 courses to Ukraine as part of their humanitarian response. As of May 2023, it was unclear whether these donated courses are in addition to the 300,000 courses that Ukraine procured in December 2021 or in lieu of the purchased courses. If the 200,000 courses were added to Ukraine's procured supply of Paxlovid (resulting in a new total of 500,000 courses for Ukraine), the total procured supply for LMICs in this scenario would be 1,116,120 courses, or 12.2 percent of health need.

Source: Duke Global Health Innovation Center Launch and Scale Speedometer; WHO Therapeutics Dashboard; COVID Treatment Quick Start Consortium

Health Need for Paxlovid in LMICs during 2022

To determine the population-based need for Paxlovid in 2022, we consider the total number of infections in LMICs that would have benefitted from the use of Paxlovid had it been available. Paxlovid is indicated for patients with non-severe COVID-19 at the highest risk of hospitalization. While reliably identifying those at the highest risk is challenging, the World Health Organization has determined that patients with older age, immunosuppression, and/or chronic diseases are the typical characteristics of high-risk patients.¹⁹ The lack of COVID-19 vaccination is an additional risk factor that is particularly significant in some non-HIC settings.

Airfinity, a health analytics company, found that from the beginning of 2022 through November 2022, the population need in non-HICs surpassed nine million doses of Paxlovid.²⁰ This estimation used total infections in populations over 65 years old as the measure for high-risk infections. However, age is a faulty proxy for high-risk population groups and could result in significant underestimations, particularly in low- and middle-income countries where shorter life expectancies, when compared to high-income countries, result in a smaller percentage of the population over the age of 65. This estimate also does not capture key population groups that would benefit from Paxlovid, including WHO categories such as those with chronic diseases under the age of 65 or groups outside of high-risk populations that could benefit from treatment, such as those experiencing long COVID.²¹ The prevalence of covid-exacerbating co-infections in LMIC regions, and poor primary and booster vaccine coverage also indicate a greater need for treatment among these at-risk populations.^{22,23} Additionally, due to data constraints, the estimation only spans from the beginning of 2022 through late November 2022. These factors make this figure a significant underestimate of population need.

Using the data from Airfinity, the Duke Dashboard, and the World Health Organization, we estimate that only one tenth of population need for Paxlovid could have been met by the procured supply in 2022, resulting in the population need exceeding procured supply by over eight million courses of Paxlovid (Figure 1). This is more than eight million

¹⁹ World Health Organization, Therapeutics and COVID-19: Living Guideline, 13 January 2023, <<https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2023.1>> [accessed 27 February 27 2023].

²⁰ Airfinity. 'WTO TRIPS COVID-19 Tx'

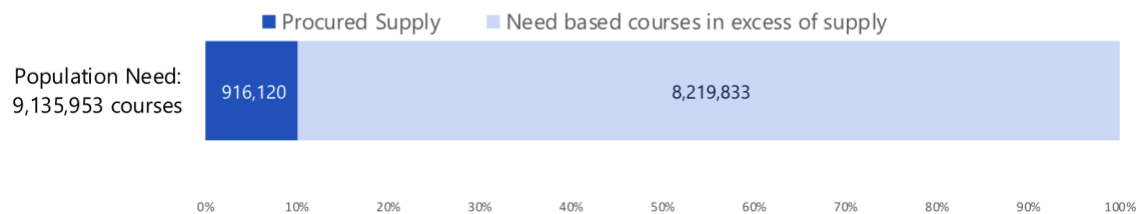
²¹ Xie, Y., Choi, T., & Al-Aly, Z., Nirmatrelvir and the Risk of Post-Acute Sequelae of COVID-19, 5 November 2022, <<https://doi.org/10.1101/2022.11.03.22281783>>

²² Nomah, DK, et al., HIV and SARS-CoV-2 Co-infection: Epidemiological, Clinical Features, and Future Implications for Clinical Care and Public Health for People Living with HIV (PLWH) and HIV Most-at-Risk Groups, *Curr HIV/AIDS Rep.*, 3 February 2022, <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8810339/>>

²³ United Nations Development Programme, Global Dashboard for Vaccine Equity, <<https://data.undp.org/vaccine-equity/>>

individuals that could have benefitted from a course of Paxlovid, potentially avoiding hospitalization or loss of life, but were not able to access the drug.

Figure 1: Population Need for Paxlovid in LMICs (2022)



Source: Airfinity; Launch and Scale Speedometer; WHO Therapeutics Dashboard

SUPPLY CHALLENGES CONSTRAINED DEMAND FOR PFIZER'S PAXLOVID

Supply challenges – high prices, opaque purchase agreements, and delayed and unpredictable supply – suppress demand and, subsequently, access to drugs for populations in developing countries.

High prices and opaque purchase agreements made it challenging for developing countries to compete with high-income countries for the initially limited supply of Paxlovid, and left LMICs to purchase supply that would be unavailable for months at prices that were unaffordable for governments. To our knowledge, the lowest reported price paid for Paxlovid in a bilateral deal with Pfizer in 2022 was US\$250 – nearly 50% of the average per capita health spending in upper middle-income countries and 200% in lower middle-income countries.^{24,25} The lack of transparency in supply agreements also prohibited countries from having a sense of the full pricing landscape and complicated the decision-making environment for purchasers.

In July 2022, the WHO Director-General said, “Our organizations are still trying to finalize with Pfizer the appropriate terms and conditions for low and middle-income countries... This is delaying access and some countries may choose to wait for a generic version of the antiviral, probably available only early 2023 and this will cost lives.”

Without supply of Paxlovid, countries could not realistically scale-up robust test-to-treat programming that rely on their ability to rapidly deploy treatment. These programs are

²⁴ Consejo de Gabinete aprueba la compra del antiviral Paxlovid de Pfizer, <<https://www.laestrella.com.pa/nacional/220125/consejo-gabinete-aprueba-compra-antiviral-paxlovid-pfizer>>

²⁵ World Health Organization Global Health Expenditure Database, <<https://apps.who.int/nha/database/Select/Indicators/en>>

essential in generating demand and creating a system to effectively distribute the therapeutic.

PREPARING FOR THE NEXT PANDEMIC

The availability of COVID-19 tests and treatments during the public health emergency was critical in mitigating the virus's impact and preventing even greater devastation than was seen. But the benefits of these tools accrued disproportionately to wealthy countries that controlled the vast majority of test and treatment supply. At least 90% of health need for the WHO-preferred COVID-19 treatment went unmet in low- and middle-income countries in 2022. The advent of a highly transmissible variant could expose this inequity once more.

Funding shortfalls and declining political will reduced uptake of medical tools against COVID-19. High prices, opaque purchase agreements and delayed, unpredictable supply also contributed to suppressed demand. Amidst ongoing negotiations of a new Pandemic Treaty and amendments to the International Health Regulations, the release of the USITC's public report on COVID-19 diagnostics and therapeutics must ground the conversations about pandemic preparedness, prevention, and response in the important learned lessons from the COVID-19 emergency.

Countries have the opportunity to enshrine these lessons in a global pandemic architecture that supports a just and equitable response to the next pandemic. Upstream access conditions, technology sharing and support for overcoming intellectual property barriers can mitigate the harms of excessive pharmaceutical industry power. Without these and other changes, poorer nations too often will be last in line for lifesaving technologies. And the mistakes of the COVID-19 pandemic will be repeated in the next.