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Open letter from civil society organizations in Latin America demanding access to Paxlovid in countries excluded from the voluntary license

Latin America and the Caribbean, March 7, 2022

Mr/Mrs

- **Dileeni Daniel-Selvaratnam**, Anguila's Governor
- **Gaston Browne**, Antigua y Barbuda's Prime Minister
- **Alberto Fernandez**, Argentina's President
- **Evelyn Wever-Croes**, Aruba's Prime Minister
- **Dr. The Hon. Hubert Alexander Minnis**, Bahamas's Prime Minister
- **Mia Amor Mottley**, Barbados Prime Minister
- **Froyla Tzalam**, Belice's Governor
- **Luis Alberto Arce Catacora**, President of Bolivia
- **Jair Bolsonaro**, President of Rep Federal de Brasil
- **Sebastián Piñera Echenique** President of Chile
- **Ivan Duque**, President of Colombia
- **Carlos Alvarado Quesada**, President of Costa Rica
- **Miguel Díaz-Canel**, President of Cuba
- **Charles Savarin**, President of Dominica
- **Guillermo Lasso**, President of Ecuador
- **Nayib Bukele**, President of El Salvador
- **Cecile La Grenade**, Granada's Governor
- **Josette Borel-Lincertin**, President of Consejo Regional de Guadalupe
- **Alejandro Giammattei Falla**, President of Guatemala
- **Irfran Ali**, President of Guyana
- **Rodolphe Alexandre**, President of Consejo Regional Guyana Francesa
- **Claude Joseph**, President E. Haití
- **Xiomara Castro**, President Honduras
- **Martyn Roper**, Premier Anwar Choudhury, Governor of Islas Caimán
- **Washington Misick**, Premier Islas Turcas y Caicos
- **Sir Patrick Allen**, General Governnor de Jamaica
- **Alfred Marie-Jeanne**, President Consejo Regional Martinica
- **Andrés Manuel López Obrador**, President of México
- **Daniel Ortega**, President of Nicaragua
- **Laurentino Cortizo Cohen**, President of Panamá
- **Mario Abdo Benítez**, President of Paraguay
- **Pedro Castillo Terrones**, President of Perú
- **Luis Abinader**, President of República Dominicana
- **Pedro Pierluisi**, Governor of Puerto Rico
- **Bruno Magras**, President of Consejo Regional San Bartolomé
- **Samuel Weymouth**, General Governor of San Cristobal y Nieves
- **Susan Dougan**, General Governor of San Vicente y las Granadinas
- **Philip J. Pierre**, Prime Minister Neville Cenac Santa Lucia's Gov
- **Chandrikapersad Santokhi**, President of Surinam

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- **Paula-Mae Weekes**, President of Trinidad y Tobago
- **Luis Lacalle Pou**, President of Uruguay
- **Nicolas Maduro**, Venezuela's President

Paxlovid¹, containing the active ingredients nirmatrelvir/ritonavir, is a drug against covid-19 that has shown promising results,² but its global distribution threatens to repeat the inequalities in access seen with vaccines. Due to its oral administration and high effectiveness, Paxlovid has been emerging as a possible turning point in the fight against covid-19. However, we are concerned that, without sound policies, in Latin America and the Caribbean its availability will be low at least in the coming months. For these reasons, we are writing to you requesting the adoption of urgent measures to guarantee access to the drug Paxlovid in our region.

Dozens of countries have already expressed interest in acquiring Paxlovid. Pfizer, the company that markets Paxlovid, has announced that it may produce around 30 million treatments globally during the first six months of 2022.³ But that amount is far less than the global demand that will exist during that period, particularly taking into account the number of projected covid-19 infections due to the omicron variant.

Pfizer is prioritizing rich countries in the distribution of Paxlovid. To date, agreements have been announced with the United States, the United Kingdom, Japan, Germany, Canada, Australia, South Korea, Spain, Israel, Italy, the Czech Republic, Belgium, and France. Taken together, those deals have already committed the 30 million Paxlovid courses that Pfizer will have available in the first six months of 2022. As Pfizer will focus on distributing Paxlovid to rich countries during the first half of the year, we expect shortages and long delays in Latin America and the Caribbean. In our region, inequalities in access to vaccines threaten to repeat themselves with respect to the antiviral Paxlovid.

This situation contrasts with the fact that nirmatrelvir is relatively easy to manufacture and numerous companies worldwide can produce it.⁴ In fact, there are already generic

¹ Paxlovid is a Pfizer brand through which the active ingredients nirmatrelvir and ritonavir are marketed.

² Paxlovid (nirmatrelvir/ritonavir) is an oral antiviral against covid-19 marketed by Pfizer. In July 2021, Pfizer initiated a Phase 2/3 study of Paxlovid in non-hospitalized adult patients with COVID-19. Individuals participating in this study had a confirmed diagnosis of SARS-CoV-2 infection within a five-day period and at least one characteristic or underlying medical condition associated with an increased risk of developing severe COVID-19 illness. . An interim analysis in that study showed an 89% reduction in the risk of COVID-related hospitalization or death compared to placebo in patients treated within three days of symptom onset. The final analysis of that study, released in December, confirmed the efficacy of Paxlovid in reducing deaths and hospitalizations.

³ Rebecca Robbins [@RebeccaDRobbins]. January 10, 2022. Pfizer says it expects to produce at least 120M treatment courses of Paxlovid this year. Bourla just gave the breakdown by quarter: Q1: 6-7M Q2: 30M cumulative Q3: ~45M Q4: ~45M. Twitter. Available

at: <https://twitter.com/RebeccaDRobbins/status/1480633419528687617?s=20>

⁴ Kevin Dunleavy, "Pfizer CEO es 50% boost to Paxlovid production—and capacity expansions, too." FiercePharma, 10 de enero de 2022. Available at: <https://www.fiercepharma.com/pharma/jpm-2022-pfizer-bumps-paxlovid->



pharmaceutical companies manufacturing or taking the final steps to start producing nirmatrelvir. More than 100 generic drug producers have expressed an interest in manufacturing this drug if they are granted a patent license authorizing its commercial distribution.⁵ Beximco in Bangladesh recently launched a generic version of this treatment.⁶ But it has not proven bioequivalence (and thus it is not clear whether other countries can rely on this product). Other companies could launch similar products in a relatively short time if intellectual property barriers are removed⁷ and a potential shortage of production inputs is addressed early.

Although nirmatrelvir does not yet have patents granted, Pfizer has applications filed in Latin American and Caribbean countries.⁸ On November 16, 2021, Pfizer and the Medicines Patent Pool (MPP) announced the signing of a voluntary license to facilitate the global manufacturing and distribution of nirmatrelvir.⁹ Pfizer licensed its patent applications and *know-how* to MPP, which in turn can now sub-license companies that make generic versions. Under the terms of that agreement, nirmatrelvir can be manufactured anywhere in the world and generic sublicensees will be exempt from paying royalties for as long as covid-19 remains listed as a public health emergency by the World Health Organization (WHO). However, under Pfizer's license to the MPP, generic sub-licensees will only be able to distribute nirmatrelvir in 95 countries. Most of the countries in Latin America and the Caribbean were left out of the MPP license, except Belize, Bolivia, El Salvador, Guatemala, Haiti, Honduras, Nicaragua, Venezuela.

Consequently, despite the license agreement with the MPP, most of the countries in our region are currently excluded and still depend on Pfizer's production capacity. The implications of this foreseeable situation are very unfair. Pfizer will ensure significant income in the most inequitable region of the globe, forcing the governments of our countries to sacrifice their poorest and most vulnerable populations. While the prices for treatment will be quite similar, the economic capacity

[production-estimate-to-120-million-for-year-while-also](#) According to Pfizer's CEO, "any decent manufacturer" can produce Paxlovid."

⁵ Viswanath Pilla y Teena Thacker. Pfizer may offer Covid antiviral drug to India at lower price for now, The Economic Times of India. 6 de enero de 2022. Available at:

enlace: <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/pfizer-may-offer-covid-antiviral-drug-to-india-at-lower-price-for-now/articleshow/88722940.cms?from=mdr>

⁶ Kerry Cullinan. Bangladesh Produces First Generic of Pfizer's Antiviral But Indian Company Hits Snag with its Merck Generic. Health Policy Watch, 11 de enero de 2022. Available at: <https://healthpolicy-watch.news/bangladesh-produces-first-generic/>

⁷ Viswanath Pilla y Teena Thacker. Pfizer may offer Covid antiviral drug to India at lower price for now, The Economic Times of India. 6 de enero de 2022. Available

at: <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/pfizer-may-offer-covid-antiviral-drug-to-india-at-lower-price-for-now/articleshow/88722940.cms?from=mdr>

⁸ Public Citizen's Report. <http://citizen.org>

⁹ "Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries." MPP. 16 de noviembre del 2021. Available at:

<https://medicinespatentpool.org/news-publications-post/pfizer-and-the-medicines-patent-pool-mpp-sign-licensing-agreement-for-covid-19-oral-antiviral-treatment-candidate-to-expand-access-in-low-and-middle-income-countries>

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of our countries is much lower and very unequal. According to Macro data, while the United States of America shows public spending on health per capita of \$8,807 US dollars, Argentina reaches \$849. While Switzerland, another top spot on Pfizer's client list, spent \$5,745, Panama spent \$590. Similar prices but resources 10 and more times lower. Colombia (\$343), Brazil (\$313) or Peru (\$187) will be forced to restrict access for the poorest, and also to assume huge debts, as has already happened with vaccines.

Even if Pfizer decides to sign agreements to distribute Paxlovid in the countries of our region, there is little guarantee that the company will meet its obligations within a reasonable time. This type of breach of the obligations in the contracts was already evidenced with the vaccines.¹⁰ Furthermore, breaches of vaccine contracts were aggravated by the fact that governments accepted confidentiality clauses, keeping the agreements secret. Pfizer continues to require these types of confidentiality clauses in Paxlovid agreements, according to statements by national authorities in our region.¹¹ The secrecy surrounding the contracts makes inspection difficult and leads to impunity.

Finally, access to nirmatrelvir is clearly a matter of public interest that justifies compulsory licensing and government use. We highlight that legal procedures have already been initiated to obtain compulsory licenses and licenses for government use in Chile and the Dominican Republic, in order to expand access to nirmatrelvir in those countries. The use of this type of flexibilities is perfectly compatible with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Granting compulsory licenses in our region would increase the supply of nirmatrelvir and guarantee its timely access at competitive prices. These measures will save lives and alleviate much of the social and economic burden that the covid-19 pandemic continues to impose on our countries.

We must draw attention to the very limited way in which our rulers have dealt with the worst global crisis in many years. The lack of solidarity and coordination in which the region has behaved in the face of the pandemic is surprising. Short-term visions, nationalisms and ideological and political positions prevailed, so that we have not had any regional initiative and little coordination, if any, between our countries.

For these reasons:

¹⁰ Rizvi Zain, "Pfizer's Power. Available at <https://www.citizen.org/article/pfizers-power/>

¹¹ Medicamentos contra COVID-19 solo para cuadros graves. Conferencia del Presidente Andrés Manuel López Obrador. 18 de enero del 2022. Available at: https://www.youtube.com/watch?v=nk6uPwiYcj0&t=7560s&ab_channel=Andr%C3%A9sManuell%C3%B3pezObrador

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1. We call on the governments of the region to implement all the flexibilities available in international agreements and national legislation on intellectual property to guarantee access to the drug nirmatrelvir in the Latin American and Caribbean countries excluded by Pfizer in your license to the MPP.
2. In particular, we demand the prompt granting of compulsory licenses and government use licenses to guarantee access to nirmatrelvir through generic manufacturers.
3. We demand transparency in relation to the negotiations and public procurement contracts signed with Pfizer related to Paxlovid. We oppose the inclusion of confidentiality clauses in such agreements and demand full transparency specifically regarding prices, the quantities of Paxlovid treatments purchased by the government, the characteristics of each lot received, and the dates by which Pfizer must make its deliveries. Transparency must be promoted with the inclusion of actors from civil society, academia, and professionals. The contracts must include the responsibilities that the producer must assume: among others, deliveries on time, responsibilities for moderate and severe adverse reactions to the drug, compensation for damages caused by the use of the drug.
4. We urge the governments of the region to implement and support initiatives for the public manufacturing of useful supplies to combat covid-19, including drugs such as nirmatrelvir, accompanied by full transparency in production costs.
5. We urge the governments of the region to implement cooperation alternatives that facilitate local production and access to treatments and vaccines for covid-19 as a way to generate autonomy for Latin America and the Caribbean in this field.

Regards,

1. Acción Internacional para la Salud, Lima, Perú
2. AID FOR AIDS_COLOMBIA
3. Alianza Lambda de Venezuela Asociación Civil
4. APROASE, A.C.
5. Aso. T.S.T.S.E.T. trabajo sexual es trabajo
6. Aso. Por Un Futuro Mejor
7. Asoc. De mujeres VIH+ Santa Micaela
8. Asociación 21 de septiembre.
9. Asociación civil de mujeres trans Amigas por Siempre del Peru
10. Asociación Civil Impulso Vital Aragua Aciva Venezuela
11. Asociación Construyendo Caminos de Esperanza frente a la injusticia el rechazo y el olvido CCEFIRO de Perú
12. Asociación Cristiana de Jóvenes. El Salvador.

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13. Asociación de mujeres autónoma primero de agosto de las trabajadoras sexuales de la provincia del Guayas
14. Asociación de Mujeres Gente Nueva -AMUGEN- Guatemala
15. Asociación de Mujeres Trabajadoras Sexuales del Cantón Milagro y la Zona 5
16. Asociación de mujeres trabajadoras sexuales por un Nuevo Amanecer la libertad Provincia de Santa Elena
17. Asociación de Mujeres trabajadoras Sexuales 16 de julio de la provincia de los Ríos
18. Asociación Goover - Ecuador
19. Asociación Las Entacaditas LOJANAS
20. Asociación Para Una Vida Mejor de Personas Infeccionadas/afectadas por el VIH-Sida en Honduras (APUVIMEH)
21. Asociación Primero de Mayo
22. Asociación PROSA, Lima, Perú
23. ASOPRODEMOS
24. Associação Brasileira Interdisciplinar de AIDS (ABIA) - Brasil
25. Associação Nacional dos Gays - ANAGAY, Brasil
26. Asociación Trans Diversa (Panamá)
27. ASUNCAMI Bolivia
28. Boquita Pintada
29. Centro de Referência e Defesa da Diversidade SP, Brasil
30. Central Nacional de Mujeres de Sectores Populares del Perú Micaela Bastidas, Sede Chiclayo.
31. Colectiva Lesbica BiSexual ANAT -Honduras
32. Colectivo Flor de Azalea
33. Corporación Innovarte, Chile
34. Corporación CONPAZES
35. Corresponsales Clave, Latinoamérica
36. Foro de la Sociedad Civil en Salud del Callao . Perú
37. Fundación Alianza Igualitaria - Ecuador
38. Fundación Arcoiris Por La Vida (FAVID) - Venezuela
39. Fundación Ecuatoriana Equidad
40. Fundación FUNDINVE - Venezuela
41. Fundación Gente Positiva Costa Rica
42. Fundación Ifarma, Colombia
43. Fundación Hábitat Verde
44. Fundación MAVID Carabobo Venezuela
45. Fundación Misión Salud, Colombia
46. Fundación Procrear (Colombia)
47. Global Humanitarian Progress Corporation GHP Corp - Colombia
48. Grupo de Incentivo à Vida (GIV) - Brasil
49. Grupo de Trabalho Sobre Propriedade Intelectual (GTPI) - Brasil
50. Grupo Pela Vidda São Paulo, Brasil

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51. Instituto para el Desarrollo Humano - Bolivia
52. Instituto Vida Nova Integração Social Educação e Cidadania, Brasil
53. ILAPYC - Argentina
54. ITPC LATCA
55. Jóvenes y adolescentes positivos de Latinoamérica y el caribe.
56. Karuna, Salud y Desarrollo - México
57. Knowledge Ecology International (KEI), USA
58. Mopaid's Movimento Paulistano de Luta Contra a Aids, Brasil
59. Movimiento Mexicano de Ciudadanía Positiva, A.C.
60. Núcleo de Estudos para Prevenção da AIDS da Universidade de São Paulo (NEPAIDS-USP) - Brasil
61. NUDHES - Grupo de Pesquisa em Saúde e Direitos Humanos da População LGBTQIA+, Brasil
62. PLAPERTS
63. Public Citizen, USA
64. RedBol
65. Red Guatemalteca Mujeres Positivas en Acción- Guatemala
66. Red Latinoamericana GayLatino - Bolivia
67. Red PVVS-Uruguay
68. RED Uruguay de PVVS - Uruguay
69. Red Venezolana de Gente Positiva RVG+
70. Salud y Fármacos - USA
71. SOMOSGAY - Paraguay
72. UAEM América Latina
73. VIHSION Festival Internacional de Cine y VIH Sida

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61. Luis Gil Abinader, República Dominicana
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