

February 6, 2024

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An Open Letter to Government Procurement Agents, International/Multistakeholder Institutions, and Charitable/Humanitarian Buyers: Say No to Secrecy in Medical Product Agreements

We write to express our deep concern about the increasing use of confidentiality and non-disclosure clauses in contracts between drug procurers and drugmakers, a secrecy harms health and access to medicine. This alarming trend must stop. We urge you, both individually and collectively, to establish a new procurement principle rejecting secrecy clauses in medical product procurement agreements. We also call on UNICEF, PAHO, PEPFAR, Gavi and The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), major procurers with significant influence, to lead efforts to make transparency a fundamental cornerstone of these critical contracts, safeguarding the health and accessibility of life-saving medicines for all.

Secrecy imposed by private industry across the entire value chain of medical products became the norm during the COVID-19 pandemic. There was secrecy with respect to many publicly funded R&D agreements and an absence of terms and conditions requiring transparency of research outcomes and conditions on commercialization. Except where certain information in select countries was guaranteed to be public, companies claimed trade secret protection concerning (1) public investments and incentives in R&D and their own private investments, (2) prices and pricing policy, (3) public and private sector procurement agreements and supply commitments, (4) contract manufacturing agreements, (5) costs of goods, (6) patent and regulatory landscapes, and more. Based on these self-proclaimed definitions of trade-secrets, major biopharmaceutical companies required confidentiality and non-disclosure agreements in procurement agreements with governments, international procurement institutions like Global Fund and UNICEF, multistakeholder initiatives like the Access to COVID-19 Tools Accelerator, and major charitable/humanitarian organizations like MSF.

These industry requirements in procurement contracts ignore the historic practice established with the global HIV response to publicly disclose supply quantities, delivery terms, and prices. This practice, achieved through concerted campaigning, helped rectify power imbalances between companies and buyers, established more affordable benchmark prices and led to more price-efficient procurement.¹

¹ For example, the Global Fund to Fight AIDS, Tuberculosis, and Malaria introduced price and quality reporting in 2005 to assist countries in negotiating better prices. Francis Wafula, Ambrose Agweyu, & Kate Macintyre, *Trends in Procurement Costs for HIV Commodities: A 7-Year Retrospective Analysis of Global Fund Data Across 125 Countries*,

With the COVID-19 pandemic, transnational biopharmaceutical companies began reversing this progress, imposing trade-secret/confidential-information protections in their procurement agreements, even when contracting with public and international procurers that are duty-bound to transparency. Their tactics include requiring purchasing partners to sign near-ironclad non-disclosure agreements.

Shielded by their non-disclosure agreements, private companies are impeding the public's interest in transparency, oversight, and accountability, fostering an environment conducive to corruption. Furthermore, they are imposing unreasonable terms and conditions, particularly for high-demand, life-saving medical products. Companies can and do make illusory promises about supply quantities and delivery terms, prevent onward donations or sales to others, set unreasonably high prices, demand onerous indemnification and guarantee provisions, retain down payments even in the event of their own breaches, and disclaim responsibility for their own intellectual property infringements.²

Based on our discussions, we understand that many of you are frustrated by the misuse of trade secret and contract law. Corporate efforts to self-define new categories of confidential information and leverage exigent circumstances, lack of competition, and contractual arm-twisting—essentially exerting unchecked commercial/monopoly power over essential health products to profit more and deliver less—must be actively resisted.

Global spending on publicly funded medical products is massive. In 2021, the United Nations system alone spent \$10.6 billion on such products.³ Government procurement agents, multilateral and multistakeholder organizations, and charitable/humanitarian buyers all have additional stewardship and public accountability obligations that are thwarted by private industry's coercive secrecy clauses.⁴ When research and development for medicines and other health technologies have been heavily subsidized by public funds, the need for transparency and accountability becomes paramount.⁵ Significant public sector investment in many health products should favor reasonable pricing and enhanced access in low-

65:4 J. Acquir. Immune Defic. Syndr. (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6616033/> (last accessed Sept. 13, 2023). Similarly, the WHO established the Global Price Reporting Mechanism for antiretroviral drugs in 2004 to provide pricing transparency for 123 countries. WHO, UNAIDS, UNICEF, *Towards Universal Access: Scaling up priority HIV/AIDS interventions in the health sector progress report 70* (2010), https://www.afro.who.int/sites/default/files/2017-06/Towards-universal-access-en_0.pdf (last accessed Sept. 13, 2023).

² Jenny Ravelo, *Big Pharma "Bullying" Revealed in South African COVID-19 Contracts*, Devex (Sept. 7, 2023), <https://www.devex.com/news/big-pharma-bullying-exposed-in-south-african-covid-19-contracts-106147> (last accessed Sept. 10, 2023).

³ UNOPS, 2021 Annual Statistical Report On United Nations Procurement 3 (2021), <https://content.unops.org/publications/ASR/2021-ASR.pdf>.

⁴ Transparency International, *For Whose Benefit?: Transparency in the Development and Procurement of COVID-19 Vaccines* (2021), <https://ti-health.org/wp-content/uploads/2021/05/For-Whose-Benefit-Transparency-International.pdf> (last access Sept. 10, 2023).

⁵ Ekaterina Cleary, Jennifer Beierlein, Navleen Khanuja, Laura M. McNamee, & Fred D. Ledley, *Contribution of NIH funding to new drug approvals 2010–2016*, 115:10 Proc. Natl. Acad. Sci. (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5878010/> (last accessed Sept. 13, 2023); Jillian Clare Dohler & Tom Wright, *The Urgent Need for Transparent and Accountable Procurement of Medical Supplies in Times of COVID-19 Pandemic*, 13:58 J. Pharm. Policy & Pract. (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7485191/pdf/40545_2020_Article_256.pdf (last accessed Sept. 10, 2023).

and middle-income countries. Companies should not be allowed to conceal the pricing of government-funded products from the public.

Fortunately, some procurers are resisting industry pressure, but they still encounter major challenges. Médecins Sans Frontières, for example, recently opposed ViiV Healthcare, the exclusive supplier of the HIV prevention drug CAB-LA, when they attempted to introduce last-minute contract provisions concealing prices and purchase agreement terms.⁶ It should be noted that the World Health Organization (WHO) has recommended this drug as a new option for reducing HIV infections.⁷ MSF's opposition to the confidentiality provisions recognizes CAB-LA's enormous public support. Of the four clinical studies the WHO reviewed in recommending the drug as a new option, three were funded by the National Institute of Allergy and Infectious Diseases in the United States.⁸ The institutions that conducted this pivotal clinical research benefited from hundreds of millions of public dollars.⁹

In recent freedom of information cases, activists in Spain and Colombia successfully established the principle that drug prices are not protected trade secrets. The Council of Transparency in Spain deemed access to this information a fundamental aspect of democracy,¹⁰ while in Colombia, the Administrative Court of Cundinamarca ruled that vaccine prices must be made public since public funds were used for their purchase.¹¹ More recently, Health Justice Initiative in South Africa also achieved a significant

⁶ Letter from Dr. Sidney Wong, Executive Co-Director, & Philip Aruna, Team Leader Southern Africa Region, Médecins Sans Frontières to Deborah Waterhouse, CEO, & Harmony Gargess, VP, Chief Medical Officer, ViiV Healthcare (Aug. 17, 2023), <https://msfaccess.org/open-letter-viiv-improve-access-hiv-prevention-drug-cab-la> (last accessed Sept. 8, 2023).

⁷ WHO, *WHO recommends long-acting cabotegravir for HIV prevention* (July 28, 2023), <https://www.who.int/news/item/28-07-2022-who-recommends-long-acting-cabotegravir-for-hiv-prevention> (last accessed Sept. 8, 2023).

⁸ HPTN 077, *Evaluating the Safety, Tolerability, and Pharmacokinetics of an Investigational, Injectable HIV Medicine (GSK1265744) in HIV-Uninfected Adults*, ID: NCT02178800, <https://clinicaltrials.gov/study/NCT02178800> (last accessed Sept. 8, 2023); HPTN 083, *Injectable Cabotegravir Compared to TDF/FTC For PrEP in HIV-Uninfected Men and Transgender Women Who Have Sex With Men*, ID: NCT02720094, <https://clinicaltrials.gov/study/NCT02720094> (last accessed Sept. 8, 2023); HPTN 084, *Evaluating the Safety and Efficacy of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women*, ID: NCT03164564, <https://clinicaltrials.gov/study/NCT03164564> (last accessed Sept. 8, 2023).

⁹ Just one grant acknowledged by Sinead Delany-Moretlwe et al. in their clinical study published in *Lancet* entailed \$682,701,894 to Family Health International in Durham, NC under the award number UM1AI068619. See COVPN 3008, MULTI-CENTER, RANDOMIZED, EFFICACY STUDY OF COVID-19 MRNA VACCINE IN REGIONS WITH SARS-COV-2 VARIANTS OF CONCERN, https://tags.hhs.gov/Detail/AwardDetail?arg_AwardNum=UM1AI068619&arg_ProgOfficeCode=104 (last accessed Sept. 8, 2023).

¹⁰ Salud por Derecho, *The Ministry of Health refuses to report the prices of several high cost medicines* (Mar. 16, 2023), <https://saludporderecho.org/en/the-ministry-of-health-refuses-to-report-the-prices-of-several-high-cost-medicines/> (last accessed Sept. 26, 2023).

¹¹ Oxfam Colombia et als., *Transparencia en la financiación y distribución para la vacunación de la Covid-19 en Colombia* (Aug. 9, 2023), <https://www.oxfamcolombia.org/transparencia-en-la-financiacion-y-distribucion-para-la-vacunacion-de-la-covid-19-en-colombia/> (last accessed Sept. 13, 2023).

victory, compelling full disclosure of procurement agreements involving Johnson & Johnson, Pfizer, Serum Institute, and Gavi's COVAX program.¹²

We realize that individual procurers may be reluctant to take solitary risks, fearing that such efforts would be symbolic (and detrimental), rather than transformative, and potentially subject them to industry retaliation. This is a classic collective action problem. Therefore, resisting these industry-imposed confidentiality provisions calls for decisive collective action focusing on greater transparency across the medical product value chain.

Key actors have acknowledged the need for transparency. In 2019, the World Health Assembly (WHA resolution 72.8) adopted a non-binding Transparency Resolution recommending increased transparency in drug pricing.¹³ In 2011, UNICEF publicly disclosed vaccine prices for the first time.¹⁴ In Europe, calls for transparency have grown, especially due to the secrecy surrounding the European Commission's COVID-19 vaccine negotiations.¹⁵ The United States has a long-standing requirement for transparency in biopharmaceutical procurement contracts,¹⁶ including during the coronavirus pandemic. Regrettably, PEPFAR has recently sidestepped transparency obligations by allowing its contracted biopharmaceutical distributor, Chemonics, to sign a non-disclosure agreement with ViiV, breaking with many years of past practices of price/supply transparency.¹⁷

These past transparency practices and current recommendations demonstrate a growing consensus that disclosure does not disrupt pharmaceutical markets. Furthermore, the claim that basic information, such as pricing, is proprietary and commercially sensitive must be challenged; price competition is a standard

¹² See Ravelo, *supra* note 2. The Constitution of the Republic of South Africa establishes an obligation for transparency in such procurement contracts. S. 217 ("When an organ of state in the national, provincial or local sphere of government, or any other institution identified in national legislation, contracts for goods or services, it must do so in accordance with a system which is fair, equitable, transparent, competitive and cost-effective").

¹³ Katrina Perehudoff, *European Governments Should Align Medicines Pricing Practices with Global Transparency Norms and Principles*, 16 *Lancet Reg. Health Eur.* 100375 (2022), [https://www.thelancet.com/journals/lanep/article/PIIS2666-7762\(22\)00068-0/fulltext](https://www.thelancet.com/journals/lanep/article/PIIS2666-7762(22)00068-0/fulltext) (last accessed Sept. 8, 2023).

¹⁴ Donald G. McNeil Jr., *For First Time, Unicef Reveals Differences in Prices It Pays Drug Companies for Vaccines*, *N.Y. Times* (May 27, 2011), <https://www.nytimes.com/2011/05/28/health/28vaccine.html>

¹⁵ See Pierluigi Russo et al., *Medicine Price Transparency and Confidential Managed-Entry Agreements in Europe, Findings from the EURIPID Survey*, 125 *Health Pol'y* 1140 (2021),

¹⁶ For example, pursuant to the Veterans Healthcare Act of 1992, pharmaceutical companies must include their brand name drug on the Federal Supply Schedule, the prices of which are public, in order to receive payment by the federal government and Medicaid. Congressional Budget Office, *Prices for Brand-Name Drugs Under Selected Federal Programs* 6 (2005), <https://www.cbo.gov/sites/default/files/109th-congress-2005-2006/reports/06-16-prescriptdrug.pdf> (last accessed Sept. 13, 2023); Office of Procurement, Acquisition and Logistics (OPAL), Department of Veterans Affairs, *Pharmaceutical Prices*, <https://www.va.gov/opal/nac/fss/pharmprices.asp> (last accessed Sept. 13, 2023).

¹⁷ Brook K. Baker, *Pharma Pricing Secrecy Runs Amok*, *Health GAP Blog* (August 17, 2023), <https://healthgap.org/pharma-pricing-secrecy-runs-amok/>.

market function and claims that concealing prices fosters innovation are dubious.¹⁸

We believe it is time for the largest procurers of medical products, including UNICEF, PAHO, Global Fund, PEPFAR and Gavi to act individually to adopt new transparency policies and collectively to support the adoption and enforcement of a new common standard that rejects secrecy, and that supports more robust, accessible reporting of procurement contract terms and agreements. Similarly, governments should reject coercive non-disclosure agreements, and simultaneously they should clarify or modify their freedom of information and drug procurement laws to ensure that supply, price, and distribution terms are publicly available. Civil society organizations concerned with access to medicines stand ready to engage in consultations on this important initiative.

Sincerely,

Public Citizen

Health GAP

People's Vaccine Alliance

Acción Internacional para la Salud - Perú

Africa Japan Forum

AIDS Healthcare Foundation

American Jewish World Service

Amnesty International

Association For Promotion Sustainable Development

Association of Women of Southern Europe – AFEM

AVAC

Brot für die Welt, Germany

Cancer Alliance, South Africa

COALITION OF WOMEN LIVING WITH HIV AND AIDS (COWLHA) – MALAWI

Colectivo TLGB Bolivia

CSYM HUDUMA*MBUENET MTANDAO COALITIONS TZ EAST AFRICA

DISABILITY PEOPLE'S FORUM UGANDA

Doctors for America

Frente Nacional por la Salud de los Pueblos del Ecuador (FNSPE)

Fundamental Human Rights & Rural Development Association (FHRRDA)

Global Fund Advocates Network (GFAN)

Global Humanitarian Progress GHP Corp

Global Justice Now

Harm Reduction International

¹⁸ Robin C. Feldman & Charles Tait Graves, *Naked Price and Pharmaceutical Trade Overreach*, 22 Yale J.L. & Tech. 61, 97 (2020), https://repository.uclawsf.edu/cgi/viewcontent.cgi?article=2771&context=faculty_scholarship (last accessed Sept. 26, 2023).

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Interfaith Center on Corporate Responsibility (ICCR)
IRUSA (Islamic Relief USA)
ITPC-MENA
Just Treatment
Vacunas para la Gente Latinoamérica
Medical Impact
Misión Salud
Muslim Aid Initiative Nigeria (MAIN)
ONG LES BATISSEURS
Oxfam
Partners In Health
People's Health Movement - PHM
People's Health Movement Korea
People's Health Institute
People's Vaccine Alliance
PrEP4All
Public Eye
Red Nacional de personas viviendo con el VIH y sida en Bolivia (REDBOL)
RESULTS
Salud por Derecho
School Sisters of Notre Dame Collective Investment Fund
Sinatsisa Lubombo Women and girls Empowerment organization
Sisters of Charity of Saint Elizabeth
Sisters of St. Francis of Philadelphia
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