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RAPID SHIFT FROM GLOBAL TO NATIONAL PURCHASE OF TB DRUGS INCREASES RISK OF STOCKOUTS AND USE OF DRUGS OF UNKNOWN QUALITY

Activists urge international donors and country governments to ensure access to quality health products as domestic financing policies push programs to the edge of procurement cliff

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The Hague, Netherlands – 26 October 2018 — Global activists at the 49th Union Conference on Lung Health in The Hague opened up a pop-up TB drug warehouse to warn about the dire public health consequences of a rushed shift from Global Fund supported pooled procurement of tuberculosis (TB) drugs and other health products to domestic funding and national procurement systems. The activists warned that without proper measures in place, access to affordable and quality-assured TB medicines and other health products for millions of people around the world is at risk.

Médecins Sans Frontières (MSF), Treatment Action Group (TAG), AIDS & Rights Alliance for southern Africa (ARASA), Global Tuberculosis Community Advisory Group (TB CAB), Health GAP, International Indigenous Working Group on HIV & AIDS, LHL International, Stop TB Partnership – Kenya, TALAKU Community, Tunisian Center for Public Health, Wote Youth and Development Projects, and Zimbabwe National Network of People Living with HIV (ZNNP+) set up a booth resembling a drug warehouse and passed out mock medicine packs labeled with “TB medicines of the future (quality unknown).”

Immense investments by the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and other donors over the past two decades have dramatically improved global access to affordable, quality-assured medicines and other commodities for TB, HIV, and malaria.

However, following stagnating financial support from donors and new Global Fund policies relating to transition and sustainability, several low- and middle-income countries will soon become ineligible for future Global Fund support, including for the procurement of essential

drugs and diagnostics. The Global Fund is providing these countries with step-down funding to purchase these essential commodities to treat and diagnose HIV, TB, and malaria. Without action, many of these countries will not have an appropriate safety net in place to guarantee sustainable access to quality and affordable drugs and diagnostics when step-down support from Global Fund ends.

Many countries shifting to domestic purchase of TB medicines do not require quality-assurance or provide waivers for the import of unregistered drugs. And the shift to domestic funding for procurement often means a loss of access to globally negotiated price reductions. Some countries are already experiencing shortages of key medicines, endangering patients' lives.

Activists called on the Global Fund and international donors to establish flexible and supportive mechanisms necessary to prevent stock outs and ensure continued access to quality-assured TB drugs and other commodities in countries that are increasing their proportion of, or fully transitioning to, domestically financed procurement.

“Prematurely requiring countries to fund procurement without preparation to mitigate risks could rollback the fragile gains made by TB, HIV, and malaria programs over the last two decades,” said Erica Lessem, Deputy Executive Director of Programs at Treatment Action Group. “People affected by TB have a right to the quality, accessible, affordable, and available interventions they need. Donors and countries have done so much to advance these rights, and should not squander those investments now.”

Countries that receive Global Fund support are required to procure medicines that have been quality assured by the WHO Pre-Qualification Program or a stringent drug regulatory authority (SRA), including those that have not yet been locally registered. To satisfy these requirements, many countries purchase TB medicines through global pooled purchasing platforms, such as the Global Drug Facility (GDF). In implementing the Global Fund's policies requiring increased domestic co-financing, countries must revert to national laws that often require procurement of locally manufactured products (which often do not exist or if they do, are pricey or of unknown quality).

“Before exiting a country, the Global Fund must ensure that national programs can maintain access to the GDF, especially in countries with smaller markets that if left alone will not have the negotiating power, laws, and policies necessary to keep products available and affordable,” said Lynette Mabote, Southern and East Africa Regional Programs Lead at ARASA. In many countries, legislative action will be required to establish a regulatory framework and other safeguards to ensure continued access to the sustainable supply of quality and affordable medicines the GDF offers.

“We have seen countries fall off a procurement cliff: first-line TB drug stock outs are happening in countries in Eastern Europe because drugs were never locally registered; pediatric ARV formulation stockouts have happened in a country in South Asia because the company awarded the tender through a national competitive bidding process could not deliver the product; and stockouts of ARVs occurred in a West African country that was asked to co-finance procurement

beyond what its system could handle,” said Sharonann Lynch, HIV and TB Policy Advisor at MSF Access Campaign.



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About AIDS & Rights Alliance for southern Africa (ARASA): Established in 2002, the AIDS and Rights Alliance for Southern Africa (ARASA) is a regional partnership of 115 non-governmental organizations working collaboratively in 18 countries in southern and east Africa to promote human rights in the context of HIV, tuberculosis (TB), and sexual and reproductive health and rights (SRHR). The ARASA partnership promotes inclusivity of all communities (in their diversity) in advocating for enabling national legal and policy environments to advance equitable and equal access to affordable health services.

About the Global TB Community Advisory Board (TB CAB): The TB CAB is a group of strong, research-literate community activists from HIV and TB networks in Asia, Europe, Africa, and North and South America. Founded in 2011, the TB CAB acts in an advisory capacity to: product developers and institutions conducting clinical trials of new TB drugs, regimens, diagnostics, and vaccines; and provide input on study design, early access, regulatory approval, post-marketing, and implementation strategies. The TB CAB is dedicated to increasing community involvement in TB research and access to tools to fight TB, and mobilizing political will.

About Health Global Access Project (Health GAP): Health GAP is an organization of AIDS and human rights activists, people living with HIV/AIDS, public health experts, fair trade advocates and concerned individuals who campaign against policies of neglect and avarice that deny treatment to millions and fuel the spread of HIV. We are dedicated to eliminating barriers to universal access to affordable life-sustaining medicines for people living with HIV/AIDS as key to a comprehensive strategy to confront and ultimately stop the AIDS pandemic. We believe that the human right to life and to health must prevail over the pharmaceutical industry's excessive profits and expanding patent rights002E

About International Indigenous Working Group on HIV & AIDS (IIWGHA): IIWGHA's mission is to create an international voice and structure that links Indigenous peoples with their Indigenous leadership, varying levels of governments, AIDS service organizations, cooperatives, and others in a global collective action to lower the disproportionate impact of HIV and AIDS experienced by Indigenous peoples.

About LHL International: LHL International was established as a foundation 01.01.2013 by the Norwegian Heart and Lung Patient organization (LHL). LHL was founded in 1943 as a special interest group for people with TB. The organization fought against prejudice, and promoted TB patients' right to work and social security. LHL International's aid work, which started in the 1980s, builds on this history. Today, LHL International has partners and projects in Malawi, Tanzania, Sudan, Zambia, Russia, Romania and Norway, mostly funded through grants from the Norwegian government.

About Médecins Sans Frontières (MSF): MSF is an international, independent medical humanitarian organization that provides medical assistance to people affected by conflict, epidemics, disasters, or exclusion from healthcare. MSF's teams are made up of tens of thousands of health professionals, logistic and administrative staff - bound together by MSF's charter. MSF's actions are guided by medical ethics and the principles of impartiality, independence and neutrality. MSF is a non-profit, self-governed, member-based organization. MSF was founded in 1971 in Paris by a group of journalists and doctors. Today, MSF is a worldwide movement of more than 42,000 people.

About Stop TB Partnership – Kenya: The STOP TB Partnership – Kenya is a movement of individuals and organizations from the Government of Kenya, corporate community, patient community and the people of Kenya who are dedicated to eliminating tuberculosis (TB) and reduction of poverty-related diseases in Kenya. The movement mirrors the Global Stop TB Partnership, which comprises of donors, national and international organizations, government and non-governmental organizations, affected communities and academic institutions working together to reduce the burden of TB worldwide and ultimately achieve a world free of TB.

About TALAKU Community: TALAKU COMMUNITY BASED ORGANIZATION: TALAKU COMMUNITY is a non-profit organization which was founded in 2012 by a former TB patient. Its main goals are to educate the community on the signs and symptoms of TB, measures of preventing and caring for TB patients. The importance of treatment adherence, contact tracing for family members and tracing lost to follow up. TALAKU educates the pastoral community on adequate measures on preventing Zoonotic TB.

About Treatment Action Group (TAG): TAG is an independent, activist, and community-based research and policy think tank fighting for better treatment and prevention, a vaccine, and a cure for HIV, TB, and hepatitis C virus (HCV). TAG works to ensure that all people with HIV, TB, and HCV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions.

About Tunisian Center for Public Health: The Tunisian Center for Public Health works collaboratively with academics and community partners to design and implement research and develop intervention strategies for urban and vulnerable populations. The Center utilizes research findings to provide tangible benefits to communities, reduce health care disparities, and foster public health care quality improvement.

About Wote Youth and Development Projects: Wote Youth Development Projects was established as an advocacy group for HIV/AIDS in 2002 using participatory interactive media mode. The youth use drama, skits, dance, role plays and football for ACSM. Currently we are implementing a CFCS TB project with STOP TB Partnership as Ambassadors of Hope.

About Zimbabwe National Network of People Living with HIV (ZNNP+): ZNNP+ is committed to be the leading national organization for advocating and lobbying for the rights of PLHIV to improve their quality of life. Our goal is to assist in ensuring that the infected and affected (by HIV and AIDS) have access to holistic care and support, prevention, treatment and mitigation in a transparent and accountable manner and to ensure that the infected and affected participate in decisions that affect them at all levels.