

MEMORANDUM OF UNDERSTANDING
between
United States Agency for International Development
and
The Medicines Patent Pool Foundation

I. Purpose

The United States Agency for International Development (hereinafter referred to as “USAID”) and the Medicines Patent Pool Foundation (hereinafter referred to as “MPP”) share a common interest and goals in addressing the need to accelerate the introduction of quality, affordable new medicines for select diseases that disproportionately affect developing countries.

II. Background

USAID and MPP (hereinafter jointly referred to as “Parties”) both recognize the burden HIV places on health systems of developing countries. Both organizations have initiatives to alleviate such burden recognizing current and future challenges in this area.

The UNAIDS Fast-Track treatment goals have called for nearly doubling the number of PLHIV on ART by 2030, reaching a total of 30 million people. The UNAIDS has estimated that in order to achieve the 90-90-90 target, roughly US\$10 billion per year will be required for global antiretroviral treatment. In the context of stagnant levels of donor funding, and limited LMIC country budgets, there is a need for simpler, better, safer, and more cost-effective HIV treatment to be made available sooner. The emergence of new products - such as treatment options with improved tolerability profiles, higher resistance barriers, and lower costs – has potentially significant health and budgetary benefits. There is a growing need to advance treatment options in developing countries by accelerating the market entry of such new products.

MPP and USAID already collaborate as part of OPTIMIZE, which is a USAID-funded global consortium with a five-year cooperative agreement (AID-OAA-A-15-00069). The OPTIMIZE project is dedicated to rapidly improving treatment outcomes for PLHIV by optimizing ARV drugs and formulations and accelerating their introduction in low- and middle-income countries.

The objective of this Memorandum of Understanding (“MOU”) is to establish a framework for the Parties to collaborate for achieving the Purpose of this MOU, while supporting their collaboration through OPTIMIZE.

The “Parties” have identified the goals and opportunities set forth below, and seek to share their respective knowledge, information, strengths, experience, technologies, and methodologies in order to achieve their common objectives:

- Facilitate early introduction of affordable newer medicines, formulations and combinations for HIV and other diseases of mutual interest as mutually identified, in low- and middle-income countries;
- Facilitate early development of optimized new ARV formulations and combinations and manufacturing approaches, including those prioritized by the OPTIMIZE consortium;

- Synergize their antiretroviral market shaping activities in PEPFAR priority countries, including under the OPTIMIZE consortium through best efforts to pool together their respective market intelligence, supplier engagement, and technical capabilities; and,
- Explore the opportunity to collaborate in other synergistic areas in access to HIV/AIDS medicines.

The Parties enter into this MOU while wishing to maintain their own separate and unique missions and mandates, and their own accountabilities. Unless specifically provided otherwise, the cooperation among the Parties as outlined in this MOU shall not be construed as a partnership or other type of legal entity or personality. Each Party shall accept full and sole responsibility for any and all expenses incurred by itself relating to this MOU. Nothing in this MOU shall be construed as superseding or interfering in any way with any agreements or contracts entered into among the Parties, either prior to or subsequent to the signing of this MOU. Nothing in this MOU shall be construed as an exclusive working relationship. The Parties specifically acknowledge that this MOU is not an obligation of funds. The Parties agree that the remaining Sections of this MOU are not intended to be legally binding commitment or create any rights in any third party.

II. Parties' Roles, Responsibilities and Notices

1. USAID

USAID Background

USAID is an independent federal government agency that receives overall foreign policy guidance from the Secretary of State. USAID implemented its first HIV/AIDS programs in 1986 and currently supports the implementation of Emergency Plan HIV/AIDS (PEPFAR) programs in nearly 100 countries, through direct in-country presence in 50 countries and through seven regional programs in the remaining countries. As a development agency, USAID has focused for many years on strengthening primary health care systems in order to prevent, and more recently to treat and care for, a number of communicable diseases, including HIV/AIDS. USAID is uniquely positioned to support multi-sectoral responses to HIV/AIDS that address the widespread impact of HIV/AIDS outside the health sector in high-prevalence countries. In these countries, USAID is supporting programs, in areas such as agriculture, education, democracy, and trade, linked to HIV/AIDS and which mutually support the objective of reducing the impact of the pandemic on nations, communities, families, and individuals.

USAID's Role

Under the Parties' collaboration, USAID's role will be to:

- Share with MPP:
 - List of PEPFAR priority countries for early adoption and uptake of new HIV drugs;
 - USAID procurement demand for specific ARVs and relevant distribution strategies in LMICs, especially those covered under the PEPFAR program;
 - Price-elasticity feedback from USAID for various ARVs, especially new formulations at the aggregate (i.e., not manufacturer specific) level;

- Provide feedback on MPP's prioritization of new ARVs and innovative technologies that could improve the prevention and treatment of HIV, including but not limited to, providing feedback on MPP's annual priority report;
- In accordance with the OPTIMIZE Cooperative Agreement, explore opportunities to support or finance development of prioritized products, including incentivizing the development and commercialization or scale-up of improved novel formulations or important niche products;
- In accordance with the OPTIMIZE Cooperative Agreement, develop strategic product introduction plans for key ARVs in LMICs, as supported through OPTIMIZE in PEPFAR priority countries;
- Facilitate dissemination of information from MPP relating to status of development and likely cost of new generics and novel formulations/combinations with relevant US government agencies such as USFDA and USAID supply chain group;
- Facilitate discussions with US government agencies relating to clarity on regulatory matters for products jointly identified by the Parties being of strategic importance;
- Continue to explore other areas of potential collaboration in achieving joint goals in the HIV sector.

All notices to USAID shall be sent to the following USAID Point of Contact:

U.S. Agency for International Development
 Emily Harris
 Health Science Specialist
 Office of HIV/AIDS
 Research Division
 2100 Crystal Drive, #9030
 Crystal City, Virginia, 22202
 Phone: 571-551-7225
 Email: emharris@usaid.gov

2. MPP

MPP Background

MPP is a UNITAID-founded non-profit organization committed to improve the health of people living with HIV, hepatitis C and tuberculosis in low- and middle-income countries (LMICs) by increasing access to quality, safe efficacious and affordable medicines by facilitating access to intellectual property on antiretrovirals, development of appropriate drug formulations needed in LMICs, and bringing to market in LMICs, novel medicines and technologies. MPP is one of the implementing partners of the OPTIMIZE consortium.

MPP's Role

Under the Parties' collaboration on HIV, it is expected that MPP's role will be to:

- Share on a regular basis with USAID:
 - Introduction time frame of important, new ARV formulations;
 - Expected cost of new formulations, where applicable;
 - Country-level expected availability and regulatory filing of ARVs for new medicines, including those countries under the PEPFAR program;

- Forecasted use and uptake of various ARVs including current and new medicines; and,
 - Other market information and technical inputs deemed necessary by the Parties;
- Seek feedback from the USAID on MPP's prioritization of new ARVs and innovative technologies that could improve the prevention and treatment of HIV;
- Encourage its licensees to prioritize regulatory filing of new ARV formulations in PEPFAR countries identified by USAID;
- Encourage its licensees to prioritize harmonization efforts around packaging, labelling and other aspects of product design or communication;
- Collaborate on product introduction efforts, including for commercialization or scale-up of new formulations or manufacturing approaches;
- Continue to explore other areas of potential collaboration in achieving joint goals in the HIV sector.

All notices to MPP shall be sent to the following MPP Point of Contact:

Medicines Patent Pool
 Attn: General Counsel
 Rue de Varembe 7, 5th floor
 Geneva, 1202
 Switzerland
 Phone: +41 22 533 50 50
 Email: office@medicinespatentpool.org

3. Other opportunities of collaborations

The Parties will explore the opportunity to coordinate and synergize their efforts on improving access to medicines for other disease areas of mutual interest. The Parties note that MPP's mandate as of now only covers HIV, HCV and TB.

III. Confidentiality and Communications

1. Communications

The Parties intend to collaborate on the development of outreach materials for external audiences, including but not limited to, joint communications and announcement regarding their collaboration. Any public announcements through press releases, media advisories or other similar means regarding this MOU or the work of the Parties hereunder shall require the prior written approval of the Parties hereto prior to such announcements. On submission of a draft press release or similar to a Party, the receiving Party shall review and provide comments to the sending Party within five (5) business days of receipt.

2. Confidentiality

The Parties will respect each other's confidentiality policies, with the mutual understanding that the Parties intend to publicize their alliance and its objectives without disclosing any confidential or proprietary information of the other Party.

IV. Effective Date, Duration, Amendments, and Termination

This MOU becomes effective on the date of the last signature of both Parties and is expected to continue for five (5) years from such effective date. However, the Parties may decide, in writing, to extend this period. In addition, this MOU may be modified or amended if all Parties agree in writing. Any Party may terminate this MOU at any time but should endeavor to provide at least thirty (30) days' written notice to the other Party.

IN WITNESS WHEREOF, the Parties, each acting through their duly authorized representatives, have caused this MOU to be signed in their names and delivered as of this 20 day of September 2017.

**UNITED STATES AGENCY FOR
INTERNATIONAL DEVELOPMENT**

By:



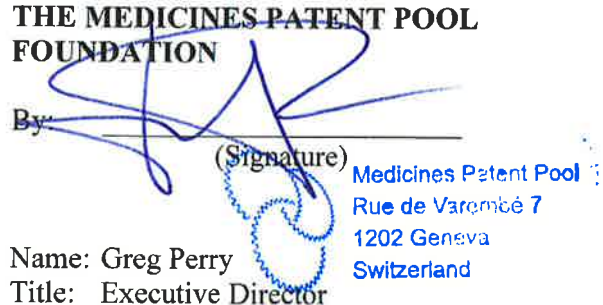
(Signature)

Name: Irene Koek
Title: Acting Assistant Administrator

Date: October 16, 2017

**THE MEDICINES PATENT POOL
FOUNDATION**

By:



(Signature)

Name: Greg Perry
Title: Executive Director

Date: 27 October 2017

Medicines Patent Pool
Rue de Varembé 7
1202 Geneva
Switzerland