
**MEMORANDUM OF UNDERSTANDING
BETWEEN THE MEDICINES PATENT POOL FOUNDATION
AND ICAP AT COLUMBIA UNIVERSITY**

This Memorandum of Understanding (“MOU”) is made as of 18 May 2017 by and between the Medicines Patent Pool Foundation (“MPP”), a not-for-profit corporation organised under the laws of Switzerland, whose business headquarters is located at Rue de Varembe 7, 1202 Geneva, Switzerland, and ICAP at Columbia University (“ICAP”) with a principal address at 722 West 168th Street, New York, NY, 10032, USA, which are referred to collectively as the “Parties” and individually as a “Party”.

Background:

As momentum towards the UNAIDS 90-90-90 targets and implementation of the World Health Organization (WHO) Treat All recommendation grows, there will be an unprecedented demand for antiretroviral (ARV) drugs. ARV spending in low- and middle-income countries (LMICs) is expected to increase from US\$1.75 billion in 2014 to US\$3.8 billion in 2020 in response to this growing demand. In the context of stagnant levels of donor funding, and limited treatment budgets of LMICs, there is a need for simpler, better, safer, and more cost-effective HIV treatment to be used as soon as possible.

The emergence of new drugs and formulations such as dolutegravir, tenofovir alafenamide, ritonavir-boosted atazanavir and darunavir as treatment options with potentially improved tolerance profiles, higher resistance barriers, and lower costs, may have significant health and budgetary benefits. In other periods of significant ARV product innovation, major time lags between initial regulatory approval to generic introduction in resource-limited, high HIV burden settings has delayed utilisation of treatment advancements for the populations that needed them most. Similar delays at this critical juncture in the HIV epidemic may prevent the rapid uptake of game-changing new ARVs for many patients.

MPP is committed to improving the health of people living with HIV, hepatitis C and tuberculosis in LMICs by increasing access to quality, safe, efficacious, and affordable medicines by facilitating access to intellectual property, development of appropriate drug formulations needed in LMICs, and bringing to market in LMICs novel medicines and technologies.

ICAP at Columbia University is one of the largest PEPFAR implementing partners, with 4,400 health facilities in over 20 countries and extensive experience conducting studies on HIV adherence and retention, many in partnership with local governments and organizations. ICAP is committed to providing quality and affordable health care to implement transformative solutions to meet the health needs of individuals.

MPP and ICAP recognise that a coordinated approach is needed to shorten the timelines from the development of evidence to the inclusion of optimized ARVs in global and local guidelines, as well as for national regulatory approval and uptake at scale within high-burden settings. Both ICAP and MPP are public health bodies with interests and activities to promote early

adoption of better treatments. As an example of their aligned interests, ICAP and MPP are partners with OPTIMIZE, which is a USAID-led global consortium. Leveraging the partnerships embedded in the consortium model with other major players in the global HIV treatment arena, OPTIMIZE facilitates the application of innovative approaches to accelerate the introduction of optimized ARVs within existing ecosystems to rapidly increase patient uptake at scale.

To that end, ICAP and MPP have agreed upon a framework of collaboration at individual country as well as global level to ensure greater access to treatment for PLHIV (the “Collaboration”) as follows:

(1) Description of the Collaboration.

In furtherance of their joint objectives, the Parties wish to accomplish the following objectives through the Collaboration:

- a. Synergize the Parties’ activities in facilitating market introduction and uptake of jointly identified priority medicines, with the aligned goal of accelerating affordable access to new ARV products, including novel formulations, in LMICs, particularly where ICAP operates. The Collaboration may be within the Parties’ activities in support of the OPTIMIZE consortium. In addition, the Parties will collaborate:
 - (i) on additional medicines, novel formulations, and approaches for the treatment and prevention of HIV; and
 - (ii) in countries where ICAP operates, but not necessarily covered by the OPTIMIZE consortium.
- b. Explore opportunities for collaboration in the field of tuberculosis (TB), including TB/HIV co-infection.
- c. Specifically, ICAP will:
 - (i) Strategize with MPP to identify priority countries for early adoption of select priority medicines, jointly identified by the Parties as such;
 - (ii) Inform local treatment programs, ministries of health, and other stakeholders of the likely availability and cost of priority medicines, especially new treatments, for their early adoption, in line with the joint objective of improving treatment outcomes for patients and cost effectiveness;
 - (iii) In furtherance of the objectives above, share information with MPP relating to:
 - 1) Potential requests from countries for filing of new medicines;
 - 2) Country market demand for specific medicines;
 - 3) Updated national treatment guidelines in countries, particularly progress updates on inclusion of new medicines in guidelines; and
 - 4) Other country-level intelligence and technical input deemed necessary by both Parties.
- d. To support ICAP’s work as listed above, MPP will:
 - (i) help its industry partners prioritize the regulatory filing of priority medicines in countries jointly identified by MPP and ICAP as priority countries;
 - (ii) In furtherance of the objectives above, share information with ICAP relating to:
 - 1) Introduction timeframe of important priority medicines;
 - 2) Expected cost of such priority medicines;

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- 3) Country-level expected availability and regulatory filing of priority medicines, especially new medicines;
 - 4) Forecasted use and uptake of current and new medicines; and
 - 5) Other market information and technical inputs deemed necessary by both Parties.
- e. Furthermore, the Parties are interested in leveraging their respective network of partners to collectively respond to urgencies in access to medicines. If and when ICAP identifies access challenges concerning specific medicines in a country where it operates, including stock outs and poor affordability, ICAP will promptly notify MPP, and MPP will promptly bring this to the attention of its industry partners to help mitigate such issues, along with efforts from local and international stakeholders.

(2) Funding. There is no intention or commitment to exchange funds under this. Each Party will respectively bear its own expenses, costs, risks, and liabilities arising from each Party's obligations and efforts under this MOU.

(3) Press Release and Other Communications. The signature of the present MOU will be announced through a press release agreed to by the Parties. ICAP and MPP agree to work together on such a press release immediately upon signature of this MOU. ICAP acknowledges that this MOU, in accordance with MPP policy, will be made publicly available on MPP's website and by other appropriate means. The Parties will agree on joint communication and stakeholder outreach plan etc. as the need arises. For the avoidance of doubt, the Parties will refer to the OPTIMIZE communications guidelines specifically for their collaborations within the OPTIMIZE.

(4) Confidentiality.

a) During the course of this MOU, the Parties may make available to each other certain Confidential Information (as hereinafter defined) or one party may otherwise learn of Confidential Information belonging to the other party. For purposes of this Section, "**Confidential Information**" means any and all confidential or proprietary information regarding a party or its business, including, without limitation, any confidential information that MPP has received from third party and is authorized to share with ICAP, all products, patents, trademarks, copyrights, trade secrets, processes, techniques, scientific information, computer programs, databases, software, services, research, development, inventions, financial, purchasing, accounting, marketing, fundraising and other information, whenever conceived, originated, discovered or developed, concerning any aspect of its business, whether or not in written or tangible form; provided, however, that the term "Confidential Information" shall not include information (i) which is or becomes generally available to the public on a non-confidential basis, including from a third party provided that such third party is not in breach of an obligation of confidentiality with respect to such information, (ii) which was independently developed by a party not otherwise in violation or breach of this Agreement or any other obligation of one party to the other, or (iii) which was rightfully known to a party prior to entering into this Agreement.

b) The Parties shall hold in strictest confidence any of the other party's Confidential Information; and shall not distribute, disclose or convey Confidential Information to any third

party and shall not make use of any Confidential Information for its own benefit or for the benefit of any third party. The foregoing notwithstanding, the Parties shall not be in violation of this subsection in the event that a party is legally compelled to disclose any of the Confidential Information.

c) Any legally-binding documentation entered into by the Parties in relation to this MOU and the Collaboration shall contain relevant clauses relating to confidentiality of information.

d) The obligations of this Section 3 shall continue for a period of five (5) years after the termination of this MOU.

(5) Status of MOU. The Parties agree to be bound by the provisions of Sections 4 and 5 hereof and agree that the remaining Sections of this MOU are not intended to be legally binding, and represent the framework for future discussions between the Parties in relation to the Collaboration.

(6) Effective Date, Term and Termination. This MOU is at-will and may be modified by mutual consent of authorized officials from both Parties. This MOU shall become effective upon signature by the authorized officials from both Parties and will remain in effect until modified by mutual consent of both Parties. In the absence of mutual agreement on extension by the authorized officials from both Parties, this MOU shall end on October 1, 2020. Either Party may terminate this MOU at any time by giving the other Party at least thirty (30) days' written notice.

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 18 of May 2017.

THE MEDICINES PATENT POOL FOUNDATION

ICAP AT COLUMBIA UNIVERSITY

BY: 

Name: Greg Perry
Medicines Patent Pool

Title: Executive Director
Rue de Varembe 7
1202 Geneva
Switzerland

Date: 18 May 2017

BY: 

Name: Mark Fussell

Title: ICAP Deputy Director and Chief
Operating Officer

Date: 24 May 2017