

**MEMORANDUM OF UNDERSTANDING BETWEEN MEDICINES FOR ALL INSTITUTE AND THE  
MEDICINES PATENT POOL FOUNDATION**

This Memorandum of Understanding (“**MOU**”) is made as of 20 September 2018 (“**Effective Date**”) by and between the **Medicines Patent Pool Foundation (“MPP”)**, a not-for-profit organised under the laws of Switzerland, whose headquarters is located at Rue de Varembe 7, 1202 Geneva, Switzerland and Virginia Commonwealth University (“**VCU**”), a public institution of higher education and instrumentality of the Commonwealth of Virginia, USA, with a place of business at 800 E. Leigh Street, Suite 3200, Richmond, VA 23219, on behalf of its Medicines for All Institute (“**M4ALL**”).

MPP and VCU will be referred to individually as a “**Party**” and collectively as “**Parties**” to this MOU.

**Background and objective**

I. MPP is an UN-backed non-profit that works on creating rapid access to affordable versions of life saving medicines in low- and middle-income countries (LMIC) through licensing and fostering generic competition and cost reduction. MPP works closely with public-health stakeholders to identify key priority medicines of the future, with originators to license those medicines and with generic manufacturers to ensure multiple generics become available in LMICs quickly, and prices fall due to scale economies and competition. MPP meets with most of its generic licensees for quarterly technical and progress reviews of API and finished formulations projects under its licences. MPP also works with partners to forecast demand for, and use of, medicines in therapy areas it works in.

II. M4ALL’s mission is to improve access to affordable, high-quality medicines by lowering the cost of medications, both in market and in development, as well as enhancing the security of supply chains for these essential medications. M4ALL accomplishes its mission by reducing the cost of active pharmaceutical ingredients (APIs), a major cost driver in treating infectious diseases in the developing world. There is a critical need for novel, cost-saving approaches to API production, but neither innovator drug companies nor generic manufacturers have economic incentives to develop them. M4ALL meets this need by identifying manufacturing routes that utilize the lowest-cost raw materials and most efficient tools available, thus reducing the cost and, hopefully, the prices of essential medications, while preserving manufacturer margins and thus security of supply.

III. MPP and M4ALL share a common interest in promoting access to, and cost reduction of, medicines in LMICs, especially in the fields of HIV, TB, malaria and hepatitis.

NOW, THEREFORE:

**1. Scope of Collaboration**

The parties aim to speed access to, and utilisation of, M4ALL-developed cost-effective processes by MPP licensees, resulting in cost reduction of medicines that are common priority for MPP and M4ALL. Such collaboration is expected to result in equitable and swifter access to M4ALL approaches and processes by more manufacturers; this access to, and use of, novel and more cost-effective processes is expected to help reduce cost of existing and novel global health medicines in LMICs.

The parties realise that working together will unlock synergies and increase the public health impact they could generate individually. Further, advance-planning, coordination and information sharing will help streamline activities and maximise such synergies.

## 2. Role of the MPP

Under the terms and conditions of this is MOU, the MPP agrees to:

- i. Share with M4ALL (and/or M4ALL's designated commercial implementation partners), MPP priorities, volume/demand projections, and views of other public health experts on priority medicines to assist M4ALL in prioritising target medicines for cost reduction
- ii. Share with M4ALL (and/or M4ALL's designated commercial implementation partners), updates on progress made by its licensees on API/formulation development to enable M4ALL with scheduling and planning of its own development activities
- iii. Facilitate engagements between M4ALL (and/or M4ALL's designated commercial implementation partners) and MPP licensees to understand and identify primary cost drivers in current process
- iv. Enter into appropriate technology transfer agreement(s) with VCU for obtaining M4ALL's technology(ies) and sharing them with its licensees:
  - a. Enter into appropriate technology transfer or licence agreement(s) with its licensees to disseminate M4ALL's technology/tech packs
  - b. Provide opinions to M4ALL about interest in, feasibility of, and timeframe for implementation of M4ALL technologies by MPP licensees
  - c. Facilitate M4ALL's (and/or M4ALL's designated commercial implementation partner's) efforts for technology absorption by licensees
  - d. Review progress on adoption of M4ALL technology by MPP licensees and provide updates to M4ALL
  - e. Estimate savings and impact due to use of M4ALL's technology by MPP licensees

## 3. Role of VCU/M4ALL

Under the terms and conditions of the MOU, M4ALL agrees to:

- i. Discuss with MPP, as a key public health stakeholder, prioritisation of projects to be taken up for cost reduction and targeted price to create robust uptake of the new process by industry and procurement agencies
- ii. Share with MPP, progress and status of cost reduction projects in areas of common interest on an ongoing basis
- iii. Enter into appropriate technology transfer or licence agreement(s) with MPP for MPP to sub-licence or disseminate M4ALL's technology/tech packs to manufacturers pursuant to which M4ALL (and/or M4ALL's designated commercial implementation partner) and MPP will:
  - a. Make available such technology/tech packs to manufacturers under appropriate contractual agreement
  - b. Collectively work to determine which are the technically most feasible manufacturers to receive technology transfer
  - c. Collaborate to provide assistance to manufacturers and facilitate adoption of M4ALL technology by manufacturers including through (i) M4ALL field visits if needed, and (ii) M4ALL troubleshooting if needed
  - d. Facilitate budgeting and decision making by manufacturers to induct M4ALL's technology, including providing guidance on additional manufacturing and/or QA/QC or other equipment required
  - e. Facilitate cost projections of M4ALL technology in the hands of MPP licensees

- f. Review and provide guidance about data, where needed, for DMF or formulations filings or modifications by manufacturers

#### **4. Confidentiality**

“Confidential Information” will comprise all information related to any Party, including but not limited to products under development, patents, processes, techniques, scientific information, financials, development timelines, sales report, regulatory filing plans and other information other information, whenever conceived, originated, discovered or developed, concerning any aspect of its business, whether in written or tangible form. All Confidential Information shall be identified as such in writing, either on its face or in a summary writing sent to the receiving party within fifteen (15) days of non-written disclosure.

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, without the prior, written consent of the party whose Confidential Information is proposed to be disclosed. Notwithstanding the foregoing, MPP and M4ALL shall both be permitted to disclose Confidential Information on an as needed basis to those persons or organizations with advisory or supervisory responsibility over MPP or M4ALL activities or operations, including, in the case of M4ALL, appropriate leadership (e.g. President, Provost, Dean of Engineering School) of Virginia Commonwealth University and appropriate representatives of M4ALL’s principal funder, The Bill and Melinda Gates Foundation (“BMGF”).

Neither Party is obligated to maintain in confidence or to refrain from disclosing or using any Confidential Information, if such information:

- (a) was known to the receiving Party prior to being received from the disclosing Party as evidenced by the receiving Party’s written records;
- (b) is, or without the fault of the receiving Party (or any of its Representatives), becomes part of the public domain,
- (c) is received by the receiving Party from a third party having, to recipient’s knowledge, no obligation of confidence and non-use to the other party hereto; or
- (d) is developed by or on behalf of the receiving Party without reliance on the Confidential Information as evidenced by the receiving Party’s written records.

In case of termination of this MOU, the confidentiality clause will remain binding to both parties for at least 2 years from the date of termination.

#### **5. Non-Exclusivity**

MPP acknowledges that M4ALL operates primarily under grant from BMGF. Under the terms of its grant from BMGF, VCU has committed to engage with one or more organizations (commercial implementation partners”) to assist in the dissemination and uptake of BMGF-funded M4ALL optimized processes by global health and generic manufacturers. MPP acknowledges that the arrangement described in this MOU is expressly non-exclusive.

**6. Public announcement/Press Release**

M4ALL acknowledges that all MPP MOU and licences are published in MPP’s website under MPP’s Transparency Policy.

The Parties will make joint public announcement on the execution of this MOU. Following this, the Parties are free to issue any press release or statement based on facts.

**7. Term and termination**

This MOU shall become effective on the Effective Date and shall expire 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. This MOU may be terminated by either Party upon a sixty (60) day advance written notice to the other Party.

**8. Severability**

If for any reason, any part of this MOU is held to be invalid, that ruling shall not impact the operation of such other parts of the MOU.

**9. Governing Law**

This MOU shall be governed and construed in accordance with the laws of the Commonwealth of Virginia, USA, without regard to conflict of law principles.

**10. Status of the MOU**

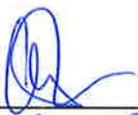
The Parties agree to be bound by the provisions of Section 4 and agree that the remaining Sections of this MOU are not intended to be binding and represent the framework for future discussions between the Parties in relation to any specific collaboration. The commencement of any activity contemplated by this MOU shall be subject to the agreement and execution of legally-binding documentation.

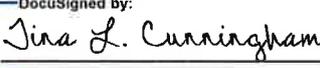
This MOU may be executed in any number of counterparts, and counterparts may be exchanged by electronic transmission (including by email), each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

In WITNESS WHEREOF, the Parties have caused this MOU to be executed by their duly authorized representatives.

**The Medicines Patent Pool Foundation**

**Virginia Commonwealth University**

By:   
Name: Chan Park  
Title: General Counsel

DocuSigned by:  
By:   
Name: Tina L. Cunningham  
Title: Associate VP for Sponsored Programs