MEDICINES PATENT POOL FOUNDATION

MEMORANDUM OF UNDERSTANDING

entered into between

Unitaid Global Health Campus Chemin du Pommier 40 1218, Le Grand-Saconnex Switzerland

and

the Medicines Patent Pool Foundation Rue de Varembé 7, fifth floor 1202, Geneva Switzerland

WHEREAS Unitaid is a global health agency with a mission to maximize the effectiveness of the global response to HIV/AIDS, tuberculosis, malaria, viral hepatitis and other priority diseases by catalysing access to better health products, and funds critical steps in the pathway to accelerating access to innovations in low- and middle-income countries (LMICs);

WHEREAS the Medicines Patent Pool Foundation (hereinafter also referred to as the "Foundation") is an independent non-profit foundation established under the laws of Switzerland to improve health by providing patients in LMICs with increased access to quality, safe, efficacious, more appropriate and more affordable health products, through a voluntary patent pool mechanism, initially in the area of antiretroviral pharmaceutical products, pediatric antiretroviral products and new fixed dose combinations for the treatment of HIV/AIDS;

WHEREAS the Foundation operates by entering into voluntary license agreements with patent holding entities, and sub-license agreements with drug manufacturers and other appropriate sub-licensees, the terms and conditions of which aim to maximize public health benefits;

WHEREAS Unitaid and the Foundation both recognise the importance of pursuing an approach which is consistent with the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property as well as being mutually supportive of instruments and declarations relating to access to medicine, such as the World Trade Organization's Declaration on the TRIPS Agreement and Public Health;

WHEREAS the aim of the Foundation is to issue sub-licenses on a voluntary, non-exclusive and non-discriminatory basis. The Foundation is open to collaborating with all interested licensors who are holders of technology of public health importance in LMICs, to licensees and sublicensees, enabling any interested party to approach the Foundation in view of seeking collaboration;

WHEREAS all LMICs are included in the scope of the work of the Foundation, and high-income countries may also be included from time to time, for example in a worldwide licence;

WHEREAS Unitaid and the Foundation seek to collaborate transparently, thereby promoting openness and public confidence;

WHEREAS the Foundation was established in 2010 by Unitaid, which remains its primary funder, with the aim of improving access to health products for the treatment of HIV/AIDS;

WHEREAS noting that the objectives and mandates of Unitaid and the Foundation are complementary and synergistic, Unitaid and the Foundation wish to take advantage of such synergies and pool resources in order to implement an effective joint fundraising strategy;

WHEREAS in accordance with Unitaid Board Resolution No. EB12/2010/R7, Unitaid and the Foundation entered into a Memorandum of Understanding (the "First MoU") on 17 September 2010 setting out the terms and conditions on which Unitaid agreed to provide funding to support the operation of the Foundation during an initial five-year period from 15 September 2010 to 31 December 2015. Under the First MoU (as amended), Unitaid provided total funding support of US \$ 31,151,121 to the Foundation;

WHEREAS at the 23rd meeting of the Unitaid Board on 4-5 November 2015, the Unitaid Executive Board adopted Resolution EB23/2015/R6 authorising the Unitaid Secretariat to expand the scope of the funding to be provided to the Foundation for the five year period from 1 January 2016 to 31 December 2020 to include funding for the hepatitis C virus ("<u>HCV</u>") and tuberculosis ("<u>TB</u>") as new disease areas in addition to HIV/AIDS;

WHEREAS in accordance with Unitaid Board Resolution No. EB21/2014/R13, Unitaid and the Foundation entered into a second Memorandum of Understanding (the "Second MoU") on 1 March 2016 setting out the terms and conditions on which Unitaid agreed to provide funding of up to US \$ 29,215,571 to support the operation of the Foundation during a further five-year period from 1 January 2016 to 31 December 2020. Under the Second MoU, Unitaid provided total funding support of US \$ 24,966,257 to the Foundation;

WHEREAS on 11 November 2020, the Unitaid Board adopted Resolution 16-2020-e, authorizing Unitaid's Executive Director to commit up to US \$ 34,270,691 to support the operation of the Foundation during a further five-year period from 1 January 2021 to 31 December 2025. The Unitaid Board's authorization for the commitment of this funding is subject to the negotiation and signature of a legal agreement between the Foundation and Unitaid;

WHEREAS Unitaid is not a separate legal entity and is hosted by the World Health Organization as ("<u>WHO</u>"). In that capacity WHO undertakes to enter into this MoU for the benefit of Unitaid (also collectively referred to as "<u>WHO/Unitaid</u>");

NOW, THEREFORE, WHO/Unitaid and the Foundation (hereinafter together referred to as the "<u>Parties</u>" and individually as a "<u>Party</u>") hereby agree as follows:

1 BACKGROUND

- 1.1 Access to treatment for HIV/AIDS through antiretroviral (ARV) drugs in LMICs is threatened by various challenges: among them increasing treatment needs, the urgent need for adapted treatments, rising drug costs and decreasing financial resources.
- 1.2 New medicines have recently become available for HCV and TB. Specifically, direct acting antivirals, which can cure infection with HCV, are revolutionizing treatment and care for HCV. New medicines for TB offer a much-needed opportunity for the treatment of challenging cases of TB, notably multi-drug resistant TB. Unfortunately, access to these new medicines is very limited for people in LMICs.
- 1.3 Patented medicines included on the WHO Essential Medicines List similarly are often not available or not affordable in LMICs. This includes several patented essential medicines necessary for the treatment of co-morbidities affecting people with HIV and TB.
- 1.4 Unitaid aims to address these and other challenges by using innovative, global marketbased approaches to improve public health by increasing access to quality products to treat, diagnose and prevent HIV/AIDS, tuberculosis, malaria and related co-morbidities in LMICs.
- 1.5 By making intellectual property available through its patent pool, the Foundation aims not only to contribute to cost reductions by enhancing competition, but also to facilitate the development of improved and new formulations, thereby expanding access to much-needed medication.
- 1.6 Considering the convergence of aims pursued by the Parties, Unitaid wishes to make a financial contribution to the Foundation and to support the activities of the Foundation as appropriate pursuant to this Memorandum of Understanding ("MoU").

2 OBJECTIVES

- 2.1 The declared mission statement of the Foundation is to improve health by providing patients in LMICs with increased access to quality, safe, efficacious, more appropriate and more affordable health products, including through a voluntary patent pool mechanism, initially in the area of antiretroviral pharmaceutical products, paediatric antiretroviral products and new fixed dose combinations.
- 2.2 According to its Statutes, the Foundation shall operate a patent pool through which intellectual property is made available, in order to reduce prices, improve access and facilitate the development and production of quality, safe and efficacious health products for use in LMICs, pursuing all such lawful activities as may be appropriate to attain its purpose.
- 2.3 In order to attain its purpose, the Foundation may *inter alia* proceed with any of the activities recited in Article 4 of the Foundation's Statutes.

3 DURATION OF THE MEMORANDUM OF UNDERSTANDING

- 3.1 The Parties agree to cooperate during the project period starting 1 January 2021 and ending 31 December 2025 (hereinafter the "Project Period").
- 3.2 This MoU may be terminated by the Parties in accordance with the provisions of Article 14 (Termination and Winding Down) below.
- 3.3 Unless terminated by the Parties in accordance with the provisions of Article 14 of this MoU, the Parties shall be free to negotiate the further extension of this MoU in good faith upon expiration of the Project Period.

4 ORGANISATIONAL STRUCTURE

- 4.1 The Foundation has its registered headquarters in Geneva, Switzerland. It has offices in Geneva and Mumbai, India.
- 4.2 The Foundation has an organisational structure, operations and activities administered in accordance with the Foundation's Statutes and internal rules, regulations and policies. The Foundation is governed by a Governance Board which is independently responsible for all major decisions pursuant to the Statutes. In addition to its voting members, the Board has the capacity to invite an additional two non-voting Board participants. Through this MoU, Unitaid may recommend to the Foundation's Board the invitation of one of the non-voting Board participants.
- 4.3 Moreover, the Statutes allow for the appointment of an Expert Advisory Group, composed of experts in various key disciplines such as public health, law (including pharmaceutical patents), economics, management, and pharmaceutical science, with a broad geographical diversity. The Expert Advisory Group has a consultative function and assists the Governance Board and the Executive Director of the Foundation in key decisions.
- 4.4 Whereas the Foundation is an independent legal entity, it shall serve as a strategic implementation partner for Unitaid. Unitaid shall advocate the mission of the Foundation and contribute to the furtherance of the Foundation's purpose.
- 4.5 The Foundation shall take full responsibility for all organisational matters concerning it. In particular, there shall be no secondment of WHO/Unitaid staff members to the Foundation.
- 4.6 As a counterpart, the Foundation shall duly report to Unitaid on the use of Unitaid funding according to the provisions of Article 0 (Reporting and Audit) of this MoU.

5 DESCRIPTION OF KEY ACTIVITIES AND DUTIES

5.1 Under this MoU, Unitaid will:

- (a) Provide the Foundation with an amount of up to US \$ 34,270,691 to facilitate the latter's activities during the Project Period. The amount to be disbursed each calendar year will be within the Budget for such calendar year attached to this MoU as <u>Annex 2</u> and approved by Unitaid on an annual basis in accordance with Articles 6.7 and 6.8 (Provision and Use of Funds). Disbursements will be made in accordance with the Schedule of Key Project Events attached to this MoU as <u>Annex 4</u>, subject to Unitaid's annual evaluation of satisfactory performance in accordance with the provisions of Article 6.11 (Provision and Use of Funds);
- (b) Use all reasonable efforts to assist the Foundation in the implementation of its outreach and communications strategy with respect to the activities set out in the Project Plan attached to this MoU as <u>Annex 1</u>;
- (c) Review the achievements of the Foundation on a regular basis; to this end, assess the reports on the progress achieved in implementation of the pool provided by the Executive Director of the Foundation.
- 5.2 Under this MoU, the Foundation will implement the activities described in the Project Plan with a view to achieving the annual targets set out in the Logframe attached to this MoU as <u>Annex 3</u>. The Project Plan and Logframe may be updated on an annual basis in accordance with Article 6.7 (Provision and Use of Funds) of this MoU.
- 5.3 If the Foundation subcontracts any of its obligations and/or activities to be carried out under this MoU, it shall do so only to duly qualified third parties of reputable standing and with a sound financial status and track record.
- 5.4 The Foundation will use all reasonable efforts to support and assist Unitaid in its work, including through the provision of specialist technical expertise and assistance with respect to patents and intellectual property matters, to support the development and implementation of Unitaid funded projects or interventions, together with Unitaid's strategic and policy positioning in this field.

6 PROVISION AND USE OF FUNDS

- 6.1 The amount payable under this MoU by WHO/Unitaid to the Foundation each calendar year shall be within the Budget and approved by Unitaid on an annual basis in accordance with Articles 6.7 and 6.8 (Provision and Use of Funds) of this MoU.
- 6.2 The amount of each disbursement of funds shall be determined on the basis of evidence of the Foundation's cash needs. The format for the Foundation's disbursement requests will be provided to the Foundation by Unitaid. The amounts presented by the Foundation in disbursement requests shall be subject to Unitaid's approval and the Unitaid Secretariat may require additional substantiation in support of the amounts requested. The final amounts disbursable will be determined and notified to the Foundation by Unitaid.

- 6.3 The Foundation will submit disbursement requests to the Unitaid Secretariat in accordance with the timelines set out in the Schedule of Key Project Events. Unitaid will make the disbursement within one calendar month of the amount being agreed.
- 6.4 The Foundation will account to Unitaid for any unexpended balance at the end of each calendar year and this amount shall be offset by Unitaid against future disbursements to the Foundation.
- 6.5 The first disbursement will include an amount which will be an estimate of the Foundation's funding requirements for approximately five months of operation. This amount will serve as a Rolling Advance throughout the duration of the term of this MoU, in order to ensure that the Foundation remains in funds during any interval from the end of a reporting period until the next requested disbursement is reviewed and released by Unitaid. Unitaid may nevertheless adjust the amount of the Rolling Advance or withdraw it entirely, in line with the Foundation's actual needs, following reasonable notice to the Foundation. The Rolling Advance will be taken into account in the calculation of the final disbursement under this MoU. The Foundation will be required to report on the use of the funds through the reporting mechanisms under the MoU.
- 6.6 The opening cash balance of Unitaid funding held by the Foundation as at 1 January 2021 will be taken into account when calculating the amount of the first disbursement to be made to the Foundation pursuant to this MoU.
- 6.7 Each year, in accordance with the timelines set out in the Schedule of Key Project Events, the Foundation will review the ongoing validity of the Project Plan, the Budget and the Logframe. Following this review, the Foundation will submit to Unitaid: (i) any requested amendments to the Project Plan or Logframe (if any); and (ii) a revised Budget for the forthcoming year and a preliminary budget for future years. The revised Budget and any amendments to the Project Plan or the Logframe will be subject to Unitaid's formal written approval.
- 6.8 For the avoidance of doubt, Unitaid's approval of the Budget each year will constitute final approval of the annual budget for the forthcoming calendar year only. Unitaid's approval of the annual budget for future years will constitute preliminary approval. The annual budget for each calendar year will remain subject to final approval by Unitaid in the preceding year.
- 6.9 Once agreed by both Parties, any amended Annexes shall form an integral part of this MoU, in accordance with Article 11.3 (Consultation and Amendment).
- 6.10 The Foundation will notify Unitaid as soon as reasonably possible, in the event that a significant expense variation is foreseen for any work stream and /or cost type included in the approved Budget.
- 6.11 Once a year Unitaid shall conduct an evaluation to evaluate whether the Foundation's performance has been satisfactory in accordance with the timelines set out in the Schedule of Key Project Events. The evaluation will be based on the Foundation's reports submitted to Unitaid in accordance with Article 8 (Reporting and Audit) and as set out in

the Schedule of Key Project Events. Further funding for the following calendar year will be conditional upon a finding of satisfactory performance. In case of unsatisfactory performance of the Foundation following an annual evaluation, Unitaid shall be entitled to terminate this MoU pursuant to Article 14.4 (Termination and Winding Down) below.

7 DISBURSEMENT SCHEDULE, PAYMENTS AND OTHER FINANCIAL PROVISIONS

- 7.1 The following arrangements shall apply with respect to payments by WHO/Unitaid to the Foundation:
 - (a) <u>Currency of payment:</u> US Dollars (US\$) shall be used for the purposes of all of the Foundation's disbursement requests to Unitaid, as well as for Unitaid's payments to the Foundation unless, on the basis of consideration of the exchange rates and/or the Foundation's currency needs, the Parties agree that it may be preferable to use Swiss Francs (CHF). In all cases, the value of the payment disbursed will be recorded in US\$ against the overall value of the grant to the Foundation. The prevailing United Nations rate will be used for the conversion of CHF to US\$ for these purposes. Unless otherwise agreed by the Parties, the Foundation's reports to Unitaid shall be submitted in both CHF and USD, and the prevailing United Nations rate will be used for the conversion of CHF to USD for this purpose.
 - (b) <u>Interest</u>: All payments to the Foundation shall be deposited into an interest bearing account held by the Foundation. The Foundation will report on interest income in its financial reports to Unitaid and shall take reasonable measures to optimize interest income within the limits set by the Foundation's financial policies. Any interest accrued on the funds transferred by WHO/Unitaid on the aforesaid account shall exclusively be used by the Foundation for activities covered by this MoU, as agreed to with Unitaid, or be transferred to WHO/Unitaid in accordance with Article 7.3 (Disbursement Schedule, Payments and other Financial Provisions) below.
 - (c) <u>Bank accounts:</u> The details of the Foundation's bank accounts are as follows:

<u>US\$ Account:</u> SWIFT: Clearing: Bank Name: Beneficiary Account Number:

Beneficiary Name:

IBAN Medicines Patent Pool Foundation

<u>CHF Account:</u> SWIFT: Clearing: Bank Name: Beneficiary Account Number: IBAN: **Beneficiary Name:**

- 7.2 The Foundation undertakes to ensure that:
 - (a) all expenses funded by Unitaid are reasonable, necessary and exclusively incurred for the benefit of the Foundation, and are incurred in accordance with the Project Plan. The Foundation further warrants that all such expenses shall comply with the Foundation's existing organizational and financial policies, as well as its applicable accounting framework. To the extent that the Foundation's existing organizational and financial polices as well as its applicable accounting framework do not provide sufficient guidance, then the Foundation shall handle such expenses in conformity with generally accepted financial standards;
 - (b) all expenses funded by Unitaid are duly approved and documented; and
 - (c) it exercises due diligence in mitigating risks resulting from exchange rate fluctuations in connection with expenses in currencies other than US Dollars. The Foundation agrees to use its best efforts in evaluating such risks and in taking appropriate steps in agreement with Unitaid to minimize any adverse impact on the activities to be carried out under this MoU.
- 7.3 Any unexpended balance of the WHO/Unitaid funds disbursed to the Foundation which is remaining at the completion of the activities of the Foundation or on termination of this MoU pursuant to Article 14 (Termination and Winding Down) shall be held by the Foundation at the disposal of WHO/Unitaid, after all obligations incurred in pursuance of the Project Plan and in accordance with the agreed budget prior to such completion or termination have been fully liquidated.
- 7.4 The Parties shall use all reasonable efforts to address any problems that may arise with regard to any budgetary matters to achieve the effective implementation of the Project Plan.
- 7.5 In the event that the Foundation fails materially to meet its obligations under this MoU, Unitaid may, after advance consultation with the Foundation, suspend all future payments to the Foundation hereunder, provided that Unitaid first provides to the Foundation a written notice of Unitaid's intent to suspend payment and such notice of suspension: (i) shall specify the exact nature of the material failure; and (ii) shall permit the Foundation a reasonable time (not less than 10 working days after receipt of the notice by the Foundation) to remedy the failure set forth in the notice. If after 10 working days or any other such reasonable time as specified in the notice of suspension the Foundation continues to be in material breach of its obligations under this MoU, Unitaid may terminate this MoU pursuant to Article 14 (Termination and Winding Down) below.

8 REPORTING AND AUDIT

8.1 In order to ensure efficient use of the funds granted by Unitaid to the Foundation under this MoU and to evaluate the needs of the Foundation in terms of assistance and strategic implementation cooperation, the Foundation shall provide periodic written progress reports to Unitaid on the use of Unitaid funds in accordance with the timelines set out in the Schedule of Key Project Events attached to this MoU as Annex 4.

- 8.2 The progress reports to be submitted by the Foundation will include the following components:
 - (a) A financial report on the use of Unitaid funding, unless otherwise agreed between the Parties, in both CHF and USD in the format of the template to be provided by Unitaid using the prevailing United Nations rate for the conversion of CHF to USD;
 - (b) A programmatic report on the progress made implementing the activities set out in the Project Plan including: (i) a monitoring and evaluation report setting out the progress of the Foundation against the annual targets included in the Logframe to be submitted using Unitaid's online reporting system; and (ii) a narrative report in the format of the Narrative Reporting Template attached as <u>Annex 5</u> to this MoU.
- 8.3 If Unitaid deems necessary, it may request a meeting with the Executive Director and/or the Chair of the Foundation's Executive Board in order to discuss the issues contained in the reports.
- 8.4 All activity and financial reporting relating to the use of Unitaid funds may be subject to audit by Unitaid and/or parties designated by Unitaid. The Foundation will promptly provide Unitaid with a copy of all statutory financial audits performed by its statutory auditor. In addition, Unitaid may also require the Foundation to instruct its statutory auditor to perform such additional special purpose financial examinations as deemed necessary by Unitaid. In order to facilitate financial reporting and audit, the Foundation shall keep accurate and systematic books of accounts and financial records in respect of the Patent Pool. In addition, the Foundation shall ensure that any obligations entered into and all disbursements made are satisfactorily documented by receipts or other bona fide documentation. For the purposes of activity reporting and audit, the Foundation shall maintain readily accessible operational information and documentation on the progress made in the implementation of the Project Plan, and shall make such operational information and documentation.
- 8.5 Unitaid may commission independent external Reviews ("<u>Reviews</u>") of the Foundation at any time during the term of this MoU. Such reviews shall be carried out at Unitaid's expense, by external independent consultants selected by Unitaid. The Foundation shall be informed of the outcome of the selection process in advance of the appointment of the selected consultants. The final appointment of the consultants shall be subject to verification by Unitaid that the Foundation has no reasonable objections to the choice of consultants. For the purposes of any such Review, the Foundation shall maintain accurate, readily accessible operational information and documentation on the progress made in the implementation of the Patent Pool. It shall make such operational information and the independent consultants, in a manner consistent with the Foundation's reasonable confidentiality obligations towards third parties, at their first request and shall provide any requested information, together with clarifications and satisfactory explanations to all queries, in a

timely manner. The Foundation shall also ensure that members of the Foundation's personnel are available to provide information and clarifications to the independent consultants at their request, on reasonable notice. The programmatic reports submitted in accordance with Article 8.2 (Reporting and Audit), together with any reasonable comments on the part of the Foundation, shall be taken into account when determining the scope of the Terms of Reference for the Review. The outcome of any Review may be used by the Unitaid Secretariat for the purposes of its evaluation of the Foundation and non-confidential elements of the Review may form the basis of the Secretariat's reports to Unitaid's Executive Board. A copy of the final version of any Review conducted in accordance with this Article 8.5 will also be provided to the Foundation. Further dissemination of the Review by either Party will nevertheless be restricted, in view of the likelihood that the Review will include information of a sensitive and confidential nature.

8.6 The Foundation will report annually to Unitaid on any real or potential conflicts of interest which have been declared under its conflict of interest policy, as set out in the Foundation's By-laws, and the measures that the Foundation has put in place to resolve such conflicts.

9 INTERIM FUNDING FOR EML EXPANSION

- 9.1 The Parties acknowledge that: (i) on 10 December 2019, the Foundation entered into a Contract with the Swiss Agency for Development and Cooperation ("SADC") pursuant to which the SADC agreed to provide funding of up to CHF 1,743,038 to the Foundation during the period from 1 January 2020 to 31 December 2022 for the inclusion of selected patented essential medicines from the WHO Essential Medicines List within the scope of work of the Foundation ("EML Expansion"); and (ii) funding from the SADC may only be used to finance a maximum amount of 50% of the total budget for the EML Expansion, and is subject to the Foundation securing funding from an alternative source for the remaining 50%.
- 9.2 Unitaid will provide funding up to an amount of CHF 1,743,038 to cover up to 50% of the costs of the EML Expansion for the period ending 31 December 2022, in accordance with the agreed Budget. Funding will be subject to advance agreement between the Foundation and Unitaid on a Prioritization Framework for selection of medicines from the EML for inclusion in the scope of the Foundation.
- 9.3 Unitaid's funding for the EML Expansion will be provided on an interim basis. In the event that the Foundation secures alternative sources of funding for this activity for the period to 31 December 2022, Unitaid's funding commitment under this MoU will be reduced by the commensurate amount. If the new funder is able to cover Unitaid's EML Expansion funding commitment in full, Unitaid's funding commitment with respect to the EML Expansion will come to an end and the total funding commitment under this MoU will be reduced accordingly. For the avoidance of doubt, funding available in the agreed Budget to the EML Expansion is not fungible and may not be attributed to any other activities or outputs funded under this MoU.
- 9.4 The Foundation will share its proposed Prioritization Framework with Unitaid and submit the selection of prioritized medicines from the EML for which Unitaid is providing funding

(up to 50% of such medicines) no later than 30 June 2021. The Parties will confer and agree to ensure that the proposed selection of prioritized medicines is relevant to Unitaid's scope of work. Such agreement shall be provided through Unitaid's formal written approval selected medicines, which will be required before work on these medicines deemed to be relevant to Unitaid scope of work are integrated into the Patent Pool. This article will remain valid for the whole duration of the financial support of Unitaid to the EML extension, up to two fiscal years. For the avoidance of doubt, Unitaid funds will only be used to finance the inclusion of medicines from the EML in the Patent Pool which are relevant to Unitaid's scope of work.

9.5 The Foundation commits to ensure the timely introduction of any modifications to its governing documents which may be necessary as a consequence of the expansion of scope (if any), as approved by the Board of the Foundation, in order to ensure compliance with Swiss law.

10 ADDITIONAL FUNDING & FUNDRAISING ACTIVITIES

- 10.1 In this MoU:
 - (a) "<u>Additional Funding</u>" means funding secured from funders or donors other than Unitaid for the financing of the Foundation during the term of this MoU;
 - (b) "Earmarked Funding" means Additional Funding that is earmarked by funders or donors for the EML Expansion detailed in Article 9 (Interim Funding for EML Expansion) or activities outside the scope of the Project Plan (such as for COVID-19); and
 - (c) "<u>Fundraising Activities</u>" means any activities undertaken for the purpose of raising or obtaining Additional Funding.
- 10.2 The Parties agree that Fundraising Activities will be conducted in accordance with the approach set out in Section 3.4 of the Project Plan.
- 10.3 The Parties will endeavor to ensure that Additional Funding is preferably paid to WHO/Unitaid for disbursement to the Foundation in accordance with the terms of this MoU. In the event that this is not possible or practical, the funds may be paid by the funder or donor directly to the Foundation. At the Foundation's request, Earmarked Funding may also be paid to WHO/Unitaid for disbursement to the Foundation.
- 10.4 Additional Funding paid by the funder or donor to WHO/Unitaid will be disbursed to the Foundation in accordance with the provisions of Article 6.2 (Disbursement Schedule, Payments and other Financial Provisions) of this MoU. Where Additional Funding from a national government is paid to WHO/Unitaid for disbursement to the Foundation, Unitaid agrees that the Foundation may describe itself as "funded by [said government] through Unitaid."
- 10.5 Any Earmarked Funding paid at the Foundation's request by the funder or donor to WHO/Unitaid for disbursement to the Foundation will be disbursed in full to the

Foundation as soon as reasonably possible following receipt of the funds by Unitaid, subject to compliance by Unitaid with WHO's internal requirements in this respect (if any).

- 10.6 With the exception of Earmarked Funding, Additional Funding will be used to fund the Project Activities in the Project Plan up to the amount set out in the Project Budget, including, without limitation, Project Activities for which Unitaid has already disbursed funding. This requirement shall apply regardless of whether the funds are paid to WHO/Unitaid for disbursement to the Foundation or paid directly to the Foundation. The Foundation will report to Unitaid in its regular financial reports on any Additional Funding paid directly to the Foundation by other funders or donors, to enable Unitaid to offset relevant funds and adjust its future disbursements to the Foundation accordingly.
- 10.7 The Foundation will ensure that any agreements entered into to secure Additional Funding are consistent with its commitments under this MoU. The Foundation will promptly provide Unitaid, in a manner consistent with the Foundation's reasonable confidentiality obligations to third parties, with any information requested by Unitaid with respect to the terms of any agreement entered or to be entered into to secure such funding.
- 10.8 For the avoidance of doubt, Unitaid will be entitled to request the amendment of the terms of this MoU as envisaged in Article 11.3 (Consultation and Amendment), with a view to ensuring that Unitaid is not disadvantaged as a result of entry into an agreement by the Foundation to secure Additional Funding.
- 10.9 Without prejudice to the generality of Article 10.8 above, in the event that any new donor providing Additional Funding (including the representative or nominee or such a donor) is granted a role in the governance in the Foundation (including without limitation a seat on the Foundation's Executive Board), the Foundation will offer to Unitaid equal rights with respect to the Foundation's governance, or equivalent rights in the event that it is not possible or feasible to grant Unitaid equal rights.

11 CONSULTATION AND AMENDMENT

- 11.1 At the request of any Party or its representatives, consultations shall take place with reference to the implementation, modification or revision of this MoU. The Parties will share relevant information as appropriate to achieve the effective implementation of the Patent Pool and address related matters of mutual concern.
- 11.2 In particular, if reasonable concerns arise as to the progress of the Project Plan, satisfactory performance of activities and obligations, achievement of milestones, or if for any reason the goals of the Foundation are not being realized, the Parties will consider alternative arrangements and modifications to the Project Plan, including, without limitation, to downsize its scope or reformulate its objectives in consultation with the Governance Board of the Foundation.
- 11.3 This MoU may be modified at any time by the mutual written consent of the Parties.

12 LIABILITY

- 12.1 Each Party shall be solely responsible for the manner in which it carries out its part of the collaborative activities under this MoU. Each Party shall be responsible for the professional and technical competence of its officials, employees, agents, subcontractors, assignees and will select, for work under this MoU, reliable individuals who will perform effectively in the implementation of this MoU, and conform to the highest standard of moral and ethical conduct.
- 12.2 A Party shall not be responsible for any loss, accident, damage or injury suffered or caused by the other Party or by a third party, or by any Party's staff or sub-contractors, in connection with, or as a result of, the collaboration under this MoU. In particular, the Foundation shall indemnify and hold harmless WHO/Unitaid for any claims, including third party claims, liabilities and/or disputes (including legal fees and costs) which may arise in connection with or as a result of, the operational activities to be performed by the Foundation under this MoU (or the activities of any of the Foundation's officials, agents, employees, subcontractors, assignees or suppliers) for which the Foundation shall assume full and sole responsibility.
- 12.3 The Foundation shall make appropriate insurance arrangements to cover liability risks covering the activities conducted by its officials, employees, agents, subcontractors, assignees relating to this MoU.

13 CONFIDENTIALITY

- 13.1 Each Party to this MoU agrees to take into account and respect commitments of confidentiality undertaken by the other Party hereto, when information is shared regarding the transactions and activities covered by the provisions of this MoU. When information provided in the context of this MoU is described by the party providing it as confidential, the receiving party shall take all reasonable measures to keep the information confidential and shall only use the information for the purpose for which it was provided. The receiving party shall ensure that any persons having access to the said information shall be made aware of and be bound by similar obligations of confidentiality and restrictions on use as contained herein.
- 13.2 However, there will be no obligations of confidentiality or restrictions on use, to the extent that the party receiving the information is clearly able to demonstrate that any part thereof:
 - (a) was known to it prior to any disclosure by the disclosing party; or
 - (b) was in the public domain at the time of disclosure by the disclosing party; or
 - (c) becomes part of the public domain through no fault of the receiving party; or
 - (d) becomes available to the receiving party from a third party not in breach of any legal obligation of confidentiality; or
 - (e) must be disclosed on the basis of a duty provided by legal provisions or a valid order of a court or other governmental authority having jurisdiction.

- 13.3 Unless another period is stipulated by the Party providing the information, the obligations of this Article shall continue for a period of ten years after the termination of this MoU.
- 13.4 The Foundation will ensure that any obligations of confidentiality undertaken to third parties in the context of the activities set out in the Project Plan including, without limitation, the obligations referred to in Articles 8.5 (Reporting and Audit) and 9.8 (Additional Funding and Fundraising Activities) of this MoU, do not go beyond what is reasonably necessary to protect such parties and the information concerned.

14 TERMINATION AND WINDING DOWN

- 14.1 The Parties may terminate this MoU at any time upon six (6) month's written notice to the Foundation with a stated reason, subject to the settlement of outstanding obligations.
- 14.2 Without prejudice to Unitaid's right to terminate in accordance with Article 14.1 (Termination and Winding Down), the Parties may also decide to terminate this MoU by mutual written consent. In this event such termination will be subject to a notice period to be mutually agreed upon between them and no less than three months.
- 14.3 If a Party becomes insolvent or any bankruptcy proceedings are instituted by or against the Party, or the Foundation has a receivership order issued against it or its assets, or the Party formally seeks any other relief from its financial obligations or if a Party breaches any of its material obligations hereunder and fails to resolve such breach within twenty (20) working days after receipt of a written notice to that effect from the other Party, that other Party will be entitled to terminate this MoU with immediate effect (in addition to such other rights it may have), subject to the settlement of any outstanding obligations.
- 14.4 In the event that Unitaid judges the performance of the Foundation, as evaluated by Unitaid pursuant to Article 6.11 (Provision and Use of Funds) of this MoU, to be unsatisfactory at the end of a funding year, Unitaid may provide a written notice of its intention to terminate this MoU. The Foundation shall have the opportunity to demonstrate its ability to remedy its unsatisfactory performance within a timeframe agreed between the Parties (but in any event no more than two (2) months). If, after the agreed-upon timeframe, the performance of the Foundation is still judged unsatisfactory by Unitaid (in its sole discretion), Unitaid shall be entitled to terminate this MoU subject to a two (2) months' written notice.
- 14.5 In cases of force majeure as set out under Article 15.3 below, the period of notice for termination of this MoU shall be of ten (10) working days.
- 14.6 In the event of termination of this MoU for whatever reason, the Parties will negotiate and agree in good faith with a view to agreeing on the most efficient, responsible, and ethical manner of winding down operations under this MoU (including compliance with any outstanding reporting obligations).
- 14.7 Upon the expiration or earlier termination of this MoU, the Foundation shall return to WHO/Unitaid any and all funds which have not been expended or committed on the Project Plan in accordance with the terms of this MoU.

15 FORCE MAJEURE

- 15.1 In this MoU, "force majeure" means any occurrence beyond the reasonable control of a Party that: (i) prevents or substantially interferes with the performance by such Party of any of its obligations hereunder; and (ii) occurs by reason of any flood, fire, explosion, earthquake, casualty or accident, or war (whether declared or not), invasion, revolution, insurrection, act of terrorism, blockage or embargo, or any unexpected government injunction, order or regulation, or other acts of a similar nature or force.
- 15.2 In the event of and as soon as possible after the occurrence of any cause constituting force majeure, the affected Party shall give notice and full particulars in writing to the other Party, of such occurrence if that Party is thereby rendered unable, wholly or in material part, to perform its obligations and meet its responsibilities under this Memorandum of Understanding and that Party shall be relieved of these obligations and responsibilities for so long as such circumstances prevail.
- 15.3 If a Party is rendered permanently unable, wholly, or in material part, by reason of force majeure to perform its obligations and meet its responsibilities under this Agreement, the other Party shall have the right to suspend or terminate this Agreement, the period of notice being of ten (10) working days.

16 COMMUNICATIONS

- 16.1 Communications activities shall be conducted by the Parties in accordance with the Communications Approach set out in the Project Plan.
- 16.2 The Parties acknowledge that public outreach and media advocacy are critical to the success of the Foundation and its ability to develop a sufficient portfolio of licences. The Parties further acknowledge that Unitaid's participation in the Foundation's public outreach and media advocacy effort is important in contributing to the success of the Patent Pool.
- 16.3 Accordingly, Unitaid agrees to fully cooperate to the maximum extent feasible in the Foundation's public outreach and media advocacy with regard to the Patent Pool. In this context, Unitaid will use all reasonable efforts to promote and advocate the Foundation's mission and goals to the extent consistent with Unitaid's mission and goals.
- 16.4 In order to implement a coordinated public communications strategy, the Parties may hold joint press conferences or publish joint press releases to announce achievements of the Foundation. Moreover, jointly-organised events may be held in furtherance of the mutually shared mission and goals of the Parties.
- 16.5 Neither Party shall make use of the logo or emblem of the other Party (including the name and emblem of WHO) without prior written permission from that other Party or WHO as the case may be.

17 DISPUTE RESOLUTION

- 17.1 The Parties shall use all reasonable best efforts to settle amicably any dispute, controversy or claim arising out of, or relating to this MoU or any other disagreement on any aspect of the implementation or execution of the activities of the Foundation. Upon request of any Party, the reasons for its dissatisfaction will be set out in writing and the cause of the dispute, controversy or claim will be discussed by the Parties involved, and the Parties shall use all reasonable efforts to resolve such dispute, controversy or claim through amicable and good faith negotiation. If after further consultations no satisfactory agreement can be reached to resolve the matter, either party may refer the matter for arbitration in accordance with the following paragraph.
- 17.2 Any matter relating to the interpretation or application of this MoU which is not covered by its terms shall be resolved by reference to the laws of Switzerland. In the event that a dispute, controversy or claim between the Parties arising out of or relating to this MoU is not settled amicably, such claim or dispute shall be settled by arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce then in effect. The Parties agree to be bound by the arbitration award rendered in accordance with such arbitration, as the final adjudication of any such dispute, controversy, or claim. The number of arbitrators shall be three. The place of arbitration shall be Geneva, Switzerland. The language to be used in the arbitral proceedings shall be English.

18 NOTICES

18.1 Any notices required under this Agreement shall be in writing and shall be delivered personally or sent by registered or certified mail or by email to the following addresses:

То:	Unitaid Executive Secretariat Global Health Campus Chemin du Pommier 40 1218, Le Grand-Saconnex
Attention: Email:	Robert Matiru. Director Operations matirur@unitaid.who.int
To:	The Medicines Patent Pool Foundation, Rue de Varembé 7, fifth floor 1202, Geneva Switzerland
Attention: Email:	Charles Gore, Executive Director cgore@medicinespatentpool.org

or such other addresses as either party shall have notified the other party. Any notice shall be deemed to have been given or made on the date it is hand-delivered, registered or confirmed to be received by recipient of the email, but any assumption of actual notice shall be subject to rebuttal to show that it has not actually been received.

19 MISCELLANEOUS

- 19.1 If during the term of this MoU, there is a change of the legal status of Unitaid, such as a change in the hosting or administering agency, such that Unitaid becomes a legal entity, the Foundation shall agree to enter into a new agreement with that legal entity under the same terms and conditions as this MoU if required by that entity.
- 19.2 The Foundation warrants that no Unitaid Board member or WHO official, including any member of the Unitaid Secretariat, or any other United Nations official has received or will be offered by the Foundation any direct or indirect benefit arising from this MoU. The Foundation agrees that the breach of this provision is a breach of an essential term of this MoU.
- 19.3 Nothing in or relating to this MoU shall be deemed a waiver of any of the privileges and immunities of WHO, including the Unitaid Secretariat by virtue of the hosting arrangement with WHO, in conformity with the Convention on the Privileges and Immunities of the Specialized Agencies approved by the General Assembly of the United Nations on November 21, 1947 or otherwise under any national or international law, convention or agreement.
- 19.4 Nothing in this MoU or the operation of the Patent Pool shall be construed in a way that could undermine, limit or interfere with domestic law and regulations of individual countries.
- 19.5 Failure of either Party to insist upon strict observance of, or compliance with, any of the terms of this MoU in one or more instances, will not be deemed to be a waiver of its right to insist upon such observance or compliance in the future.
- 19.6 The Annexes attached hereto form an integral part of this MoU. The headings used in this MoU are for convenience only and will not be construed as having any meaning in the interpretation of this MoU. In the event this MoU contains any provisions which are in conflict with any of the provisions of any of the Annexes, the provisions of this MoU shall take precedence.
- 19.7 This MoU may be executed in two or more counterparts, each of which shall be deemed an original and together shall constitute one agreement.

(Signature page follows)

IN WITNESS WHEREOF this Memorandum of Understanding has been entered into on by the duly authorised representatives of the Parties.

Agreed on behalf of the World Health Organisation acting for Unitaid

Philippe Duneton **Executive Director**

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Date: 16/11/2020

Agreed on behalf of the Medicines Patent Pool Foundation

Charles Gore **Executive Director**

Charles Com Date: 16/11/2020