

Schedule of Sample Terms and Conditions UnitaidExplore Funding Agreement

This document sets out indicative examples of legal clauses which may be included in the funding agreements of successful applicants to UnitaidExplore. Applicants should ensure that they are able to agree to each of the terms and conditions in this document prior to submitting their application for funding under UnitaidExplore. The clauses below do not however, constitute an entire agreement. Some may be omitted or changed, at Unitaid's sole discretion, whilst additional clauses will also be included in the funding terms offered to successful applicants, as relevant.

Applicants should also note that Unitaid is hosted by the World Health Organization (WHO) and is not a separate legal entity. Successful applicants will therefore be invited to conclude UnitaidExplore Funding Agreements with WHO, which will act for and on behalf of Unitaid in this respect.

1 Project Funding

Unitaid will provide funding to the Recipient to implement the project described in the attached Project Description ("Project"). Unitaid will disburse funding for the Project ("Project Funding") in milestone payments ("Milestone Payments"), which will be made following the achievement of agreed milestones ("Milestones"). The Milestones and Milestone Payments are set out in the attached Milestone Schedule. If any Milestone is delayed without Unitaid's prior written agreement, Unitaid reserves the right to: (i) determine that the Milestone Payment is forfeited; and/or (ii) terminate this Agreement for breach of its terms in accordance with Section 12 (Termination).

Following the achievement of each Milestone, the Recipient will submit to Unitaid: (i) an invoice in the form of the attached Invoice Template; (ii) a copy of the means of verification associated with the Milestone set out in the Milestone Schedule; and (iii) a progress report in the form of the attached Progress Report Template. The Recipient will also promptly respond to any additional requests for information from Unitaid in relation to progress on Project implementation.

2 Representations and Warranties

In this Agreement, "Tobacco Industry" means any entity involved in the manufacture, sale or distribution of tobacco and related products, and any affiliate of such entity. "Arms Industry" means any entity involved in the manufacture, sale or distribution of arms, and any affiliate of such entity.

The Recipient represents and warrants to Unitaid the following, as of the date of last signature of this Agreement ("Effective Date"): (i) the Recipient is a legal entity with full power and authority to enter into this Agreement and implement the Project, and all necessary approvals and consents have been obtained and are in full force and effect; (ii) the execution of this Agreement does not contravene the Recipient's governing documents or any legal obligations to which it is subject; (iii) the Recipient is solvent and able to pay its debts as and when they fall due; (iv) the Recipient is not, and was not over the last four years, part of the Tobacco or Arms Industries; and (v) to the best of its knowledge, the Recipient has not, over the last four years: (a) engaged in activities that are aimed at furthering or supporting the interests of the Tobacco Industry including, but not limited to, supply contracts, contract work, services and lobbying; or (b) had any other association or relationship with the Tobacco Industry including, but not limited to, investment interests (other than general mutual funds or similar arrangements whereby the Recipient has no control over the selection of the investments), commercial business interests and/or the provision or receipt of financial or other support.

3 Audit of use of Project Funding

At Unitaid's cost, the Recipient will allow Unitaid, or any entity designated by Unitaid, to audit any financial books and records, including, without limitation, accounting records, bank statements, and expense receipts, which document the use of the Project Funding. Other than where an audit is required in order to determine

whether the Project Funding has been used in breach of this Agreement, such audit will be conducted not more than once per year during regular business hours.

4 Human Subject Research

In this Agreement, “Human Subject Research” or “HSR” means any social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge in which human beings: (i) are exposed to manipulation, intervention, observation or other interaction with investigators, either directly or through alteration of their environment; or (ii) become individually identifiable through investigators’ collection, preparation or use of biological material or medical or other records. “International HSR Standards” means: (i) the Declaration of Helsinki (WMA 2013); (ii) International Conference on Harmonisation. ICH Topic E6(R2): ‘Guideline for Good Clinical Practice’ 2016; (iii) World Health Organisation ‘Good Clinical Laboratory Practice’ (ISBN 978-92-4-159785-2); and (iv) the last approved version of the International Ethical Guidelines for Health Related Research Involving Humans (CIOMS).

The Recipient will safeguard the rights and welfare of human subjects participating in Human Subject Research and will ensure that all Human Subject Research is carried out in accordance with: (i) national and local laws and regulations applicable to Human Subject Research; and (ii) International HSR Standards. In the event of any conflict between applicable national laws and International HSR Standards, the Recipient will comply with whichever standard provides the greater protection for research subjects, provided that the Recipient will not be in breach of any applicable national laws. The Recipient will ensure that appropriate terms are included in its agreements with any subcontractors responsible for carrying out Human Subject Research to ensure that the Recipient is able to comply with this obligation.

The Recipient will not commence any Human Subject Research prior to being informed by Unitaid that WHO’s Research Ethics Review Committee (“WHO ERC”) has either: (i) approved the research protocol or protocols for such Human Subject Research; or (ii) issued a decision waiving the requirement for its approval.

The Recipient will ensure that appropriate liability insurance coverage is obtained prior to the commencement of all Human Subject Research and is maintained at all relevant times. Such insurance will conform to all relevant standards and regulations and will be consistent with best practices applicable in the sponsor’s jurisdiction. It will be taken out with a reputable international insurance provider and will cover, as a minimum, claims brought against the sponsor and the principal investigator and will include WHO/Unitaid as an additional insured party. The Recipient will promptly provide Unitaid with written confirmation that such insurance has been taken out, together with a copy of the certificate and policy providing evidence of such insurance, if requested by Unitaid.

5 Intellectual Property

In this Agreement, “Health Product” means any medicines, in vitro diagnostics (IVDs) and/or medical equipment which are developed either in whole or part, or in which substantial funds are invested for the purpose of creating sustainable market conditions, under or as a result of this Agreement. Any Health Products will be identified in the Project Description. “Intellectual Property Rights” means any patent, trademark, service mark, copyright, moral right, right in a design, know-how and any other intellectual or industrial property rights, anywhere in the world whether or not registered. “Recipient Background IP” means the Recipient’s Intellectual Property Rights related to the Health Products or any component of the Health Products, that was in the Recipient’s possession prior to the Effective Date. “Recipient Foreground IP” means the Recipient’s Intellectual Property Rights related to the development of the Health Products, the process of manufacture of the Health Products or otherwise in connection with the Health Products, that was developed by the Recipient under or as a result of this Agreement.

The Recipient represents and warrants to Unitaid the following as of the Effective Date: (i) the Recipient holds

all Intellectual Property Rights existing at the Effective Date which are necessary in order to implement the Project; (ii) to the best of the Recipient's knowledge, implementation of the Project will not infringe any third party Intellectual Property Rights; and (iii) the Recipient will manage any Recipient Foreground IP in a manner which furthers and is consistent with the Access Objective (as defined in Section 7 (Access to Health Products)).

The Recipient acknowledges that Unitaid has entered into this Agreement on the basis of the representations and warranties made by the Recipient above. In the event that any representation made by the Recipient in this Section 5 (Intellectual Property) is found to have been false or misleading in any material respect, the Recipient will, following a written demand from Unitaid, reimburse all Project Funding disbursed by Unitaid.

6 Dissemination of the Project Results

In this Agreement, "Project Results" means all results, including information, knowledge, non-individually identifiable data, materials, analysis, reports, evaluations and other documents, generated by or on behalf of the Recipient as result of implementation of the Project, but not including any Recipient Background or Foreground IP.

The Intellectual Property Rights in, and ownership of, the Project Results will remain with the party having created or produced such results. Subject to the confidentiality provisions set out in Section 13 (Confidentiality), the Recipient: (i) hereby provides a non-exclusive, irrevocable, worldwide, royalty-free, sub-licensable license to WHO on behalf of Unitaid to use the Project Results for non-commercial public health, education and research purposes; (ii) will provide Unitaid and/or WHO with the Project Results, or any part thereof, promptly following a request from Unitaid; and (iii) will disseminate the Project Results promptly and broadly in the interests of public health.

In order to ensure that the Project Results may be shared and disseminated as broadly as possible in the interests of public health, the Recipient will: (i) obtain all necessary consents and authorisations to sharing of the Project Results generated by such activities with Unitaid and/or WHO including, without limitation, from relevant national and regulatory authorities, ethical review boards, consultants and sub-contractors; (ii) publish any scientific articles or chapters using or incorporating the Project Results in an appropriate open access mechanism in accordance with WHO's policy on open access (available at: <http://www.who.int/publishing/openaccess/en/>); and (iii) make the data generated by the Project publicly available on open access terms in an appropriate online data repository: (a) at the same time as publication, in relation to data supporting, or which may be necessary to validate, the main findings of any publication; and (b) no later than six (6) months after the last Milestone Payment, in relation to all other data which may have public health value.

7 Access to Health Products

The Recipient acknowledges that a key objective of the Project is to ensure that any Health Products are made widely available, as quickly as possible and on a continuing basis, at an affordable and sustainable price, to the public sector in relevant low and middle-income countries and in sufficient quantities to meet the needs of those countries (the "Access Objective"). In furtherance of the Access Objective, Unitaid and the Recipient have agreed to specific commitments in relation to affordable pricing, supply security, in-country registration and quality assurance for the Health Products (as relevant and appropriate) ("Access Commitments"). The Access Commitments, the duration of enforceability of the Access Commitments and the means for monitoring compliance with the Access Commitments are set out in the attached Access Commitments Annex.

8 Access License

In this Agreement, "Access Default" means that the Recipient: (i) commits a material breach of this Agreement which, if capable of being cured, is not cured within ninety (90) days of receipt by the Recipient of written notice from Unitaid; (ii) experiences a force majeure event which, if capable of being resolved, is not resolved within one hundred and twenty (120) days of receipt by the Recipient of written notice from Unitaid; (iii)

becomes unable to pay its debts as and when they fall due, makes any voluntary arrangement with its creditors, becomes subject to an administration order, goes into liquidation, or is subject to any other bankruptcy, insolvency or similar proceedings, such situation which is not resolved within thirty (30) days; (iv) makes a strategic decision to discontinue development and/or commercialisation of a Health Product; or (v) experiences a Change in Control or Transfer in breach of Section 9 (Change in Control or Transfer), which, if capable of being cured, is not cured within ninety (90) days of receipt by the Recipient of written notice from Unitaid. “Change in Control” means: (i) the acquisition after the Effective Date, directly or indirectly, by any person or entity, of the beneficial ownership of more than fifty per. cent (50%) of the voting share capital of the relevant entity or the ability to direct the casting of more than fifty per. cent (50%) of the votes exercisable in the relevant entity; (ii) a merger, consolidation or other similar transaction involving the relevant entity; or (iii) the sale, transfer or other disposition (in one transaction or a series of transactions) of all or substantially all of the assets of the relevant entity.

The Recipient hereby grants to Unitaid a conditional, non-exclusive, royalty-free, worldwide, irrevocable and sublicensable license to use the Recipient Foreground IP in order to research, develop, make, have made, offer-for-sale, sell, import, export and distribute the Health Products in for the benefit of the public sector in low and middle-income countries.

The Access License is conditional upon the occurrence of an Access Default. In the event of notice from Unitaid indicating occurrence of an Access Default leading to the unconditional granting of the Access License, the Recipient will work with Unitaid to take any action and/or execute any documents which may be reasonably required to complete or formalise such license of the Recipient Foreground IP to Unitaid, or an alternative industry partner nominated by Unitaid. Such action will include, without limitation, transferring and/or making available all necessary technology, know-how, and other information relating to the Recipient Foreground IP for the purpose of permitting Unitaid, or its nominated alternative partner, to utilise the Access License and facilitate the continued development, manufacture and commercialisation of the Health Products for the benefit of the public sector in low and middle income countries.

9 Change in Control or Transfer

In the event of either: (i) a Change in Control; or (ii) the license (other than in accordance with this Agreement), transfer, sale or acquisition of the Recipient Background IP and/or the Recipient Foreground IP, or substantial assets owned or controlled by the Recipient which are necessary to perform its obligations hereunder, by a third party, including as a result of a Change in Control (a “Transfer”); the Recipient will ensure that all of its obligations hereunder are assumed by the licensee, purchaser, transferee, acquirer or successor of the Recipient Foreground and/or Background IP, the Recipient’s assets or the Recipient in a written agreement acceptable to Unitaid. A breach of this provision will constitute an Access Default.

10 Right of First Refusal for Future Funding

Unitaid has a right of first refusal in relation to providing future funding for the development and/or commercialisation of any Health Products for the benefit of low and middle-income countries. The Recipient will notify Unitaid formally in writing of its desire to seek additional funding prior to approaching or requesting funds from alternative funding sources. Unitaid will make best efforts to indicate whether it is favourable to considering such request within thirty (30) days from receiving such request and any additional information requested by Unitaid for the purpose of making its decision. A final decision in relation to additional funding will be made by Unitaid in its sole discretion.

11 Term and Survival

This Agreement will come into effect on the Effective Date and will remain in effect until the date which is one (1) year after the last Milestone Payment, unless terminated early in accordance with the provisions of Section 12 (Termination).

Following expiration or in the event of early termination of this Agreement, all provisions that by their nature should survive will survive including, without limitation, Section 3 (Audit of use of Project Funding), Section 6 (Dissemination of the Project Results), Section 7 (Access to Health Products), Section 8 (Access License), Section 13 (Confidentiality), Section 14 (Indemnity and Warranties), Section 15 (No Waiver of Privileges and Immunities) and Section 16 (Resolution of Disputes).

12 Termination

If a party becomes insolvent or any bankruptcy proceedings are instituted by or against the party, or the party 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 thirty (30) days after receipt of a written notice to that effect from the other party, that other party will be entitled to terminate this Agreement with immediate effect (in addition to such other rights it may have), subject to the settlement of any outstanding obligations.

Either party may terminate this Agreement, at any time and without cause, upon three (3) months' written notice to the other party, subject to the settlement of any outstanding obligations. In the event of termination by Unitaid on three (3) months' written notice without cause where the Recipient is able to demonstrate to Unitaid's satisfaction that it was making best efforts to achieve the next Milestone, the Recipient will be entitled to receive an amount equal to fifty per cent (50%) of the next Milestone Payment.

13 Confidentiality

Information that needs to be treated as "confidential" should be clearly marked as such by the party providing it. When information provided in the context of this Agreement is marked 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.

However, there will be no obligations of confidentiality or restrictions on use, to the extent that the receiving party is clearly able to demonstrate that any part thereof: (i) was known to it prior to any disclosure by the disclosing party; or (ii) was in the public domain at the time of disclosure by the disclosing party; or (iii) becomes part of the public domain through no fault of the receiving party; or (iv) becomes available to the receiving party from a third party who is not in breach of any legal obligation of confidentiality.

The obligations of confidentiality shall continue for a period of ten years after the expiry or termination of this Agreement. Notwithstanding this Section 13 (Confidentiality), the Recipient will ensure that any obligations of confidentiality undertaken to third parties which may impact on the implementation of the Project do not go beyond what is reasonably necessary to protect such parties and the information concerned.

14 Indemnity and Warranties

The Recipient will be responsible for the manner in which all activities performed under or as a result of this Agreement are carried out (including, without limitation, activities associated with the development and/or commercialisation of any Health Products) and will indemnify and hold harmless WHO/Unitaid for any and all claims and liabilities (including legal fees and costs) arising or resulting from such activities carried out by the Recipient, its employees, authorized agents, and subcontractors.

15 No Waiver of Privileges and Immunities

Unitaid is hosted by the World Health Organization (WHO) and is not a separate legal entity. WHO therefore enters into this Agreement for and on behalf of Unitaid. Nothing in or relating to this Agreement shall be deemed a waiver of any of the privileges and immunities of WHO, including Unitaid, 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.

16 Resolution of Disputes

Any dispute relating to the interpretation or execution of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties, or in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The seat of the arbitration shall be Geneva and the language of the arbitration proceedings shall be English or French, at the discretion of the parties. The parties shall accept the arbitral award as final.

17 Compliance with WHO Policies

By entering into this Agreement, the Recipient acknowledges that it has read, and hereby accepts and agrees to comply with, the WHO Policies (as defined below). In connection with the foregoing: (i) the Recipient shall not engage in any conduct that would constitute a violation of the standards of conduct, as described in the WHO Policies; and (ii) the Recipient shall take appropriate measures to prevent and respond to any violations of the standards of conduct, as described in the WHO Policies, by its employees and any other persons engaged by them to perform the work under the Agreement.

Without limiting the foregoing, the Recipient shall promptly report to WHO, in accordance with the terms of the applicable WHO Policies, any actual or suspected violations of any WHO Policies of which the Recipient becomes aware. For purposes of this agreement, the term "WHO Policies" means collectively: (i) the WHO Code of Ethics and Professional Conduct; (ii) the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; (iii) the WHO Code of Conduct for responsible Research; (iv) the WHO Policy on Whistleblowing and Protection Against Retaliation; and (v) the UN Supplier Code of Conduct, in each case, as amended from time to time and which are publicly available on the WHO website at the following links: <http://www.who.int/about/finances-accountability/procurement/en/> for the UN Supplier Code of Conduct and at <http://www.who.int/about/ethics/en/> for the other WHO Policies.

18 Zero tolerance for sexual exploitation and abuse

WHO/Unitaid has zero tolerance towards sexual exploitation and abuse. In this regard, and without limiting any other provisions contained herein, the Recipient warrants that it will: (i) take all reasonable and appropriate measures to prevent sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response by any of its employees and any other persons engaged by it to perform the work under the Agreement; and (ii) promptly report to Unitaid and respond to, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Recipient becomes aware.

19 Anti-terrorism and UN sanctions; Fraud and Corruption

The Recipient warrants for the entire duration of the Agreement that: (i) it is not and will not be involved in, or associated with, any person or entity associated with terrorism, as designated by any UN Security Council sanctions regime, that it will not make any payment or provide any other support to any such person or entity and that it will not enter into any employment or subcontracting relationship with any such person or entity; (ii) it shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the Agreement; and (iii) it will take all necessary precautions to prevent the financing of terrorism and/or any illegal corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the Agreement.