

## GRANT AGREEMENT

This grant agreement (“**Agreement**”) is entered into as of the date of the last signature of this Agreement (“**Effective Date**”) by and between

**Medicines Patent Pool**, a non-profit organisation, whose registered office is at Rue de Varembe 7, 1202 Geneva, Switzerland (“**MPP**”);

**Wits Health Consortium (Pty) Ltd**, with registered address at 31 Princess of Wales Terrace, Parktown, Johannesburg, 2193, through its Supporting Health Initiatives division (“**WHC**”);

**Raj Long**, 4 Drill Court, Walmer England (“**Project Lead**”); and

**South African Health Products Regulatory Authority**, a juristic person established in terms of Clause 2 of the Medicines and related Substances Act 101 of 1965, as amended, whose official business address is Second Floor Building A, Loftus Park, 402 Kirkness Street, Arcadia, Pretoria (“**SAHPRA**”). SAHPRA is herein duly represented, by Dr Boitumelo Semete-Makokotlela in her capacity as the Chief Executive Officer who warrants that she is authorised to do so,

individually “**a Party**” and together “**the Parties**”.

### PREAMBLE

WHEREAS, the World Health Organization (“**WHO**”), MPP and other organisations desire to strengthen regional health security and respond more equitably to Covid-19 infections and future pandemics.

WHEREAS, they agreed to establish a sustainable mechanism that will increase vaccine manufacturing capacity in Africa and elsewhere in low- and middle-income countries, through the establishment of a technology transfer and training hub for mRNA-based vaccines, including Covid-19 mRNA vaccines (“**mRNA Technology Transfer Programme**”).

WHEREAS, as part of the mRNA Technology Transfer Programme, MPP has received funding from a third party (“**Funder**”) to use for the development and strengthening of the capacity of local regulatory authorities to assess the readiness of facilities to produce mRNA vaccines, to review mRNA vaccine authorisation applications, to perform registration and lot release functions, and to train and strengthen the capacity of other national regulatory authorities.

WHEREAS, MPP wishes to provide the funds to WHC, a wholly-owned company of the University of the Witwatersrand that provides funds management services, for the purpose of holding those funds, disbursing those funds to SAHPRA solely upon the request of Project Lead, and overseeing the use of those funds by SAHPRA, and WHC wishes to receive those funds for that purpose. MPP will not have any involvement in the disbursement of the funds to SAHPRA or the technical aspects of the mRNA regulatory activities of SAHPRA.

WHEREAS, SAHPRA, a regulatory authority that regulates health products in South Africa, wishes to receive the funds from WHC for SAHPRA to use for the mRNA regulatory strengthening and development activities in support of mRNA vaccine regulatory oversight as described above and to receive technical oversight and support from Project Lead for those activities.

WHEREAS, Project Lead is the regulatory co-lead with WHO Regulatory for the mRNA Technology Transfer Programme and, in that independent capacity, will provide technical oversight and support of the Project, as defined below, to assist SAHPRA in its mRNA regulatory strengthening and development activities, and to manage the disbursement of the funds from WHC to SAHPRA for the Project.

NOW THEREFORE, the Parties hereby agree to the following terms and conditions:

## 1. **Project**

- 1.1. Scope of Project. SAHPRA shall perform the scope of work described in Annexure 1, attached and incorporated herein ("**Project**") in accordance with the terms and conditions of this Agreement. The Project may be modified solely by mutual agreement between SAHPRA and Project Lead.
- 1.2. MPP Obligations. Without limiting any rights of MPP under this Agreement, MPP shall provide WHC with the Funds in accordance with Clause 4.1, receive the financial reports and statements under Clause 8 and the technical reports under Clause 9, and have the right to terminate this Agreement in accordance with Clause 15 of this Agreement.
- 1.3. Project Lead Obligations. Project Lead shall be the technical project lead of the Project and responsible for managing and assisting SAHPRA in the performance of the Project in accordance with the terms and conditions of this Agreement. In the event Project Lead becomes unavailable to continue with the Project, the Parties shall find a mutually acceptable substitute. In the event a mutually acceptable substitute is not found, the matter shall be resolved in accordance with Clause 17.2.
- 1.4. Key Personnel. The Project shall be performed by SAHPRA under the direction of SAHPRA's Chief Executive Officer ("**SAHPRA CEO**") with the participation of the other key individuals identified in Annexure 1, (collectively with the SAHPRA CEO, the "**Key Personnel**"). SAHPRA shall not be permitted to substitute Key Personnel during the term of this Agreement, except as necessitated by the sudden illness, death, termination of employment of such persons, in which case such persons shall be replaced with a mutually agreeable substitute. In the event a Key Personnel become unavailable to continue with the Project, SAHPRA and Project Lead shall find a mutually acceptable substitute. In the event a mutually acceptable substitute is not found, the matter shall be resolved in accordance with Clause 17.2.
- 1.5. Subcontractors. SAHPRA shall not delegate, whether by subcontract or otherwise, any of its obligations hereunder without the prior written consent of Project Lead. If a delegation is approved, SAHPRA shall flow down all obligations of this Agreement in an enforceable agreement with the delegee and shall remain liable for the performance or non-performance/breach of this Agreement by such delegee.

## 2. **Project Management**

- 2.1. Project Management. Project Lead and SAHPRA shall form a joint project management committee (the "**Project Committee**") to oversee and facilitate the implementation and execution of the Project, to review and discuss financial and technical reports and statements, and to review proposed changes to the Project scope, timeline and / or Budget (as defined below). The Project Committee shall meet virtually or in person once per quarter at mutually agreeable times and locations, and shall invite WHC (Supporting Health Initiative division) to join such meetings to review and discuss financial reports and statements. SAHPRA and WHC (Supporting Health Initiative division) shall have the right to designate their representatives (which may be consultants or adviser subject to the relevant terms and conditions set out herein) to the Project Committee and may replace their representatives upon notice to Project Lead. All decisions at the Project Committee shall be taken unanimously. In the event the consensus cannot be reached, the matter shall be submitted to the Chief Executive Officer of SAHPRA and, if concerning a financial matter, the Head of the Supporting Health Initiatives, a Division of WHC, for resolution between such persons and Project Lead; and in case the issue remains unsolved for 3 months from its first referral, the matter shall be resolved in accordance with Clause 17 "Dispute Resolution". For the avoidance of doubt, MPP shall not be part of the Project Committee.
- 2.2. Management of breaches. Without limiting any rights of MPP under this Agreement, if Project Lead becomes aware of any act or omission by SAHPRA or WHC which may in Project Lead's reasonable opinion constitute a breach of this Agreement, Project Lead shall notify MPP, as soon as reasonably practical, of details of the suspected breach and Project Lead's proposed course of action, and shall keep MPP up to date on the management of such breach, including any mitigation plan agreed with SAHPRA or WHC.

## 3. **Deliverables**

- 3.1. Completion and provision. SAHPRA shall complete each deliverable as part of the Project ("**Deliverable**") on or before the due date as specified in Annexure 1 and shall provide the Deliverables to Project Lead as part of its technical reporting under Clause 9.1 in the form of a documentary Deliverable or evidence of the completion of the Deliverable, as applicable.

3.2. Delays and issues. Notwithstanding the provision of the Deliverables as part of the technical reporting under Clause 9.1, if there is an actual or anticipated delay or issue in the completion of a Deliverable by the due date as specified in Annexure 1, SAHPRA undertakes to:

- a) promptly inform Project Lead in writing of such delay or issue; and
- b) take all steps reasonably required by Project Lead to prevent, limit, or rectify such delay or issue, including with the assistance of Project Lead.

Without limiting any Parties' rights or remedies they may have against SAHPRA for such delay or issue, Project Lead may specify a revised due date for the completion of a Deliverable. Project Lead shall promptly notify MPP of any such delay or issue by SAHPRA.

#### 4. **Grant Payment**

4.1. Grant to WHC. MPP shall pay WHC the total amount of \$2,349,064 United States Dollars ("**USD**") in accordance with the payment schedule set out in Annexure 2 Clause A ("**Funds**") via a bank transfer to the WHC general deposit account set out in Annexure 2 Clause C. Subject to Clause 15.2 "Grant Reduction", MPP shall have the right to increase or decrease the total amount of the grant.

4.2. WHC Funds management. Within 10 working days of receipt of the first payment of Funds from MPP under Clause 4.1, WHC shall open a bank account specific to the Project ("**Project Account**") and shall transfer those Funds into that Project Account. WHC shall transfer all further payment of Funds from MPP into the Project Account within 10 working days of receipt. For the avoidance of doubt, the Project Account shall not hold any funds other than the Funds received under this Agreement. The balance of the Funds held by WHC in its Project Account shall include any gain or loss to those Funds due to any applicable interest rates or foreign exchange rate.

4.3. Disbursement for the Project. Subject to the terms and conditions of this Agreement, and SAHPRA's compliance therewith, WHC shall disburse the Funds in South African Rand ("**ZAR**") to SAHPRA or Consultants (as defined below) for performing the Project in accordance with the approved budget and disbursement schedule as set out in Annexure 2 Clause B ("**Budget**"). Notwithstanding any other provision in this Agreement, no disbursement of Funds under this Agreement shall exceed the amount of Funds available and held by WHC.

4.4. Budget. The Funds disbursed by WHC to SAHPRA under this Agreement are to be spent by SAHPRA exclusively in accordance with the Budget and the Funds disbursed by WHC to a Consultant or otherwise paid or deducted from the Funds by WHC (namely bank charges and the Management Fee) shall be in accordance with the Budget. Project Lead and SAHPRA shall have the right to perform Budget revisions on a quarterly basis. Unless agreed otherwise between Project Lead and SAHPRA for a specific case, SAHPRA shall:

- a) have the right to make adjustment of +/- 15% between the Budget's categories, i.e each individual budget line; and
- b) request Project Lead's prior written approval if there is a variance of +/- 5% versus annual amounts set out in the Budget. Any request for Budget modification shall include sufficient documentation to justify such request.

For the avoidance of doubt, no Budget revision or adjustment of the Budget's categories or variance of the annual amounts set out in the Budget that is permitted under this Clause 4.4 shall result in WHC disbursing and SAHPRA spending in excess of the total Funds held by WHC. Project Lead shall notify WHC and MPP of any amendments to the Budget, including any amendments to utilise any interest or foreign exchange gains.

4.5. Disbursement Request. Project Lead shall issue a disbursement request to the Head of Supporting Health Initiatives, a Division of Wits Health Consortium, on a quarterly basis for WHC to disburse an amount of Funds (in ZAR) to SAHPRA and / or a Consultant as specified in the Budget ("**Disbursement Request**"), upon receipt and approval of the following:

- a) a WHC Quarterly Financial Statement in accordance with Clauses 8.4(a) and 8.5 for the previous quarter of spending by SAHPRA as part of the Project; and

- b) a Quarterly Technical Report in accordance with Clauses 9.1(a), 9.2 and 9.3 for the previous quarter of work performed by SAHPRA as part of the Project.

For the avoidance of doubt, except for the first Disbursement Request, Project Lead shall not issue a Disbursement Request without receipt of (a) and (b) above, or if the WHC Quarterly Financial Statement and / or Quarterly Technical Report reveal a breach of this Agreement, until such breach has been rectified. Each Disbursement Request shall be issued to the Head of Supporting Health Initiatives, a Division of Wits Health Consortium, at the address set out in Clause 13. Project Lead shall promptly notify MPP of each Disbursement Request issued to WHC.

4.6. Disbursement. Upon receipt of the Disbursement Request:

- a) for disbursement to SAHPRA, WHC shall make a disbursement of the Funds to SAHPRA in the amount in ZAR specified in the Disbursement Request within 5 days from its receipt via a bank transfer to the SAHPRA account set out in Annexure 2 Clause D; and
- b) for disbursement to a Consultant, WHC shall make a disbursement of the Funds to the Consultant after entering into a Consultancy Agreement with the Consultant in accordance with Clause 5.2 below and make such a disbursements in accordance with that Consultancy Agreement.

- 4.7. Value added tax. The Budget is inclusive of value added tax (as far as is applicable) and SAHPRA shall be solely responsible for the payment of any value added tax or other tax obligations incurred on the Funds spent by SAHPRA.

5. **WHC Consultants**

- 5.1. Consultant Request. Subject to the prior written approval of SAHPRA, Project Lead may request WHC to contract a consultant ("**Consultant**") to provide training services to human resources recruited by SAHPRA as part of the Project by issuing to WHC (i) a request for a Consultant, which shall specify the identity of the Consultant and role description that details the term, services, deliverables, fees, and payment schedule, and (ii) a Disbursement Request for WHC to disburse an amount of Funds (in ZAR) to the Consultant based on the fees of the Consultant for the relevant quarter ("**Consultant Request**").
- 5.2. Consultancy Agreement. Upon receipt of the Consultant Request, WHC shall enter into a consultancy agreement with the Consultant, in a form to be agreed by SAHPRA, for the Consultant to provide services to SAHPRA and for WHC to pay the fees of the Consultant by making disbursements of the Funds to the Consultant in accordance with the Consultant Request ("**Consultancy Agreement**"). WHC shall promptly notify Project Lead and SAHPRA upon entering into a Consultancy Agreement, including providing a copy of the Consultancy Agreement, and of all disbursements made to the Consultant.
- 5.3. WHC Obligations. WHC shall perform its obligations under the Consultancy Agreement and shall procure the Consultant to perform and comply with its obligations under the Consultancy Agreement. WHC shall notify SAHPRA and Project Lead in case of any issues or delays in the Consultant performing its obligations under the Consultancy Agreement.
- 5.4. SAHPRA Obligations. SAHPRA shall notify WHC and Project Lead in case of any issues or delays in the Consultant providing its obligations under the Consultancy Agreement. SAHPRA shall include the disbursements made by WHC to any Consultant in its financial reporting under Clause 8 and the work performed by the Consultant in its technical reporting under Clause 9.

6. **WHC Fees**

- 6.1. SHI, a Division of WHC Management Fee. In consideration of receiving and disbursing the Funds under this Agreement, WHC shall be paid management fees in accordance with the amounts and payment schedule set out in Annexure 2 Clause B ("**Management Fees**"). WHC shall receive the Management Fees by deducting it from the amount of Funds held by WHC in its Project Account and transferring it to any of its other bank accounts.

7. **Use of Funds**

- 7.1. WHC Use. WHC shall be solely permitted to disburse the Funds in accordance with the terms and conditions of this Agreement and shall not use those Funds for any other purpose unless otherwise agreed in writing by the Parties.

- 7.2. SAHPRA Use. SAHPRA acknowledges and agrees that the disbursed Funds are provided for non-commercial purposes only. During the term of this Agreement, SAHPRA shall use the Funds solely for the performance of the Project.
- 7.3. SAHPRA Performance. SAHPRA shall enter into the necessary sub-agreements (excluding with Consultants) and perform the necessary administrative activities to ensure that the Project as set out in Annexure 1 is funded and executed.
- 7.4. Equipment, Material and Goods. During the Project term, SAHPRA shall use the equipment, materials or goods, purchased or generated with the disbursed Funds provided hereunder, for the purpose of the Project only. Title to any equipment, materials or goods purchased or generated with the disbursed Funds shall vest in SAHPRA during and after the completion of the Project provided SAHPRA uses such exclusively for a purpose related to the Project or other non-commercial purposes. Upon completion of the Project or termination of this Agreement, if SAHPRA wishes to either sell, donate or otherwise transfer the said equipment, goods or materials, SAHPRA shall request prior written consent from Project Lead. Should Project Lead provide such consent, SAHPRA agrees to reimburse MPP for fair market value of such commercial use.

## 8. Financial Reports

- 8.1. SAHPRA Financial Reports. SAHPRA shall prepare and provide Project Lead and WHC with the following financial reports, and in a format to be agreed upon between MPP, WHC, and Project Lead and shared by Project Lead to SAHPRA, which may be updated from time to time:
- a) quarterly financial reports, which shall:
    - i) be sent within 10 working days after the end of each calendar quarter (with the first quarterly financial report covering the period from the Effective Date to the end of the first full calendar quarter);
    - ii) contain the comparison between the actual spending versus the budgeted amounts for the preceding quarter(s) accumulatively; and
    - iii) be certified as complete and accurate by an authorised official of SAHPRA for the activities performed,

(“**SAHPRA Quarterly Financial Report**”);
  - b) two interim financial reports, which shall:
    - i) be sent for each calendar year of the Project by no later than 31 January 2025 and 31 January 2026;
    - ii) contain the comparison between the actual spending versus the budgeted amounts during the applicable preceding calendar year; and
    - iii) be certified as complete and accurate by an authorised official of SAHPRA for the activities performed,

(“**SAHPRA Interim Financial Report**”); and
  - c) final financial report, which shall be a final report of cumulative costs incurred marked “FINAL” and shall be sent no later than 20 working days after the completion of the Project or termination of this Agreement, whichever first occurs (“**SAHPRA Final Report**”). All payments hereunder shall be provisional and subject to adjustment within the total estimated cost under this Agreement in the event such adjustment is the result of a finding against SAHPRA pursuant to Clause 10.2,

(together, “**SAHPRA Financial Reports**”).
- 8.2. SAHPRA Annual Finance Audit Statement. SAHPRA shall provide to Project Lead and WHC an audited annual statement comprising of the following by 31 January 2025 and 31 January 2026:
- a) audited annual project financial report of SAHPRA; and

- b) a questionnaire, in a format to be agreed upon between MPP and WHC (which may be updated from time to time), and provided to SAHPRA by WHC, regarding the use of funds under this Agreement. Such questionnaire shall be signed by an auditor mutually agreed upon by the Parties,

(“**SAHPRA Annual Finance Audit Statement**”).

8.3. Reporting to MPP. Within 5 working days of receipt of a SAHPRA Financial Report or SAHPRA Annual Finance Audit Statement, WHC shall provide to MPP a copy of such financial document.

8.4. WHC Financial Statements. WHC shall prepare and provide MPP and Project Lead with the following financial statements, and in a format to be shared by MPP, which may be updated from time to time:

- a) within 5 working days of receipt of a SAHPRA Quarterly Financial Report, a quarterly financial statement, which shall contain a summary of the amount of Funds disbursed to SAHPRA and / or a Consultant(s) and spent by SAHPRA during the preceding quarter, including whether the amount disbursed and spent is in accordance with the Budget, the interest gain on the Funds held by WHC, and any USD to ZAR foreign exchange rate applicable to Funds held by WHC (“**WHC Quarterly Financial Statement**”);
- b) no later than 14 February 2025 and 14 February 2026 of receipt of each SAHPRA Interim Financial Report respectively, an interim financial statement for the applicable preceding calendar year, which shall contain a summary of the amount of Funds received from MPP and disbursed to SAHPRA and / or a Consultant(s) and spent by SAHPRA during the preceding year, including whether the amount disbursed and spent is in accordance with the Budget, the interest gain on the Funds held by WHC, and any USD to ZAR foreign exchange rate applicable to Funds held by WHC (“**WHC Interim Financial Statement**”); and
- c) within 10 working days of receipt of the SAHPRA Final Financial Report, a final financial statement, which shall contain a summary of the total amount of Funds received from MPP and disbursed to SAHPRA and / or a Consultant(s) and spent by SAHPRA under this Agreement, including whether the amount disbursed and spent is in accordance with the Budget, the interest gain on the Funds held by WHC, and any USD to ZAR foreign exchange rate applicable to Funds held by WHC (“**WHC Final Financial Statement**”),

(together, “**WHC Financial Statements**”).

8.5. Review and approval of WHC Financial Statement. Project Lead shall, within 7 working days of receipt of a WHC Quarterly Financial Statement, review and approve such financial statement, and MPP shall, within 10 working days after receipt of a WHC Interim Financial Statement and WHC Final Financial Statement, review and approve such financial statements.

8.6. WHC Annual Finance Audit Statement. WHC shall provide to MPP an audited annual statement comprising of the following by the 31 December of each year:

- a) audited annual project financial report of WHC; and
- b) a questionnaire, in a format to be provided by MPP (which may be updated from time to time) regarding the disbursement of the funds under this Agreement. Such questionnaire shall be signed by an auditor mutually agreed upon by the Parties,

(“**WITS Annual Finance Audit Statement**”).

## 9. **Project Reports and Inspections**

9.1. Technical Reports. SAHPRA shall prepare and provide Project Lead and WHC with the following technical reports:

- a) quarterly technical reports, which shall be sent within 10 working days after the end of each calendar quarter and describe the progress on the Project during the applicable preceding quarter (with the first quarterly technical report covering the progress on the Project during the period from the Effective Date to the end of the first full calendar quarter) (“**Quarterly Technical Report**”);
- b) two interim technical reports, which shall be sent for each calendar year of the Project by no later than 31 January 2025 and 31 January 2026, and describe the progress on the Project during the applicable preceding calendar year; and

- c) final technical report, which shall be a final statement of cumulative work performed under the Project marked 'FINAL' and shall be sent no later than 20 working days after the completion of the Project or termination of this Agreement, whichever first occurs,

(together, the "**Technical Reports**"). In each case, such Technical Reports shall set out the work performed and achievements under the Project, including contain (i) all due documentary Deliverables or evidence of the completion of due Deliverables to be delivered as part of the Project, (ii) detail any delayed activities or overdue Deliverables, and (iii) detail the work to be performed and Deliverables to be completed during the next quarter.

9.2. Review and re-submission of Technical Reports.

- a) Project Lead shall, within 7 working days after receipt of a Technical Report, review the Technical Report (including the Deliverables contained in such Technical Reports) and either approve or provide comments on the Technical Report. If comments are provided, Project Lead and SAHPRA shall discuss such comments; and
- b) SAHPRA shall, within 5 working days of receipt of Project Lead's comments, prepare a revised Technical Report that addresses Project Lead's comments and re-submit it to Project Lead for approval.

9.3. Approval of Technical Reports. Project Lead and SAHPRA shall repeat the process in Clause 9.2 until Project Lead approves the Technical Report. For the avoidance of doubt, no act or omission of Project Lead in connection with this Clause 9 constitutes deemed approval of a Technical Report and approval of a Technical Report does not occur until Project Lead notifies SAHPRA in writing that the Technical Report has been approved.

9.4. Inspections. Project Lead, or her nominees and experts, shall have the right to inspect and review the progress of the Project at the location(s) where the Project has been performed, upon reasonable notice and at mutually agreeable times and locations. Access to facilities, relevant data, reports and Project results used or generated hereunder shall be made reasonably available when such inspections are conducted. Inspections by Project Lead shall be conducted in a manner as to not unduly delay the progress of the Project or any other activities of SAHPRA.

9.5. Reporting to MPP. Within 5 working days of receipt of a Technical Report under this Clause 9, Project Lead shall provide to MPP a copy of such Technical Report for its information.

10. **Financial Records and Audits**

10.1. SAHPRA Records. SAHPRA shall maintain supporting documentation for all costs associated with the Project, including records substantiating the expenditure of the funds provided under this Agreement. All records and documentation related to this Agreement shall be maintained in accordance with applicable laws and regulations and generally accepted accounting principles for a period of five years from completion of the Project.

10.2. SAHPRA Audit. Notwithstanding Clause 8.2, WHC or its authorised representative shall have the right to review and audit all costs alleged to have been incurred hereunder and those records required by Clause 10.1 at agreed upon times and locations. SAHPRA shall provide WHC with copies of any audit report which presents any instance of noncompliance with laws or regulations relating to the performance or administration of this Agreement. SAHPRA shall also provide copies of any response to any such report and a plan for corrective action. SAHPRA shall maintain a separate accounting cost code specific to this grant, and all costs and income properly relating to this grant shall be accounted for through that cost code. SAHPRA shall ensure that appropriate records are kept supporting the entries made on the cost code.

10.3. WHC Records. WHC shall maintain supporting documentation for all disbursements of the Funds to SAHPRA, including records of the Disbursement Requests received under this Agreement. All records and documentation related to this Agreement shall be maintained in accordance with applicable laws and regulations and generally accepted accounting principles for a period of five years from completion of the Project.

10.4. WHC Audit. Notwithstanding Clause 8.6, MPP or its authorised representative shall have the right to review and audit all disbursements of the Funds to SAHPRA and those records required by Clause 10.3 at agreed upon times and locations. WHC shall provide MPP with copies of any audit report which presents any

instance of noncompliance with laws or regulations relating to the performance or administration of this Agreement. WHC shall also provide copies of any response to any such report and a plan for corrective action. WHC shall maintain a separate accounting cost code specific to this grant, and all costs and income properly relating to this grant shall be accounted for through that cost code. WHC shall ensure that appropriate records are kept supporting the entries made on the cost code.

## 11. Confidentiality

- 11.1. Definition. “**Confidential Information**” means information which is marked with “confidential” or a similar legend upon disclosure, or if disclosed orally or observed, is designated as confidential at the time of disclosure and provided by one Party, a “**Disclosing Party**” to the other Party, a “**Receiving Party**”. Confidential Information does not include information that is: (a) already known to the Receiving Party prior to disclosure under this Agreement; (b) publicly known or becomes publicly known other than through acts or omissions of the Receiving Party, or anyone that obtained the information or materials from the Receiving Party; (c) lawfully disclosed to the Receiving Party without restriction by a third party; (d) independently developed by employees of the Receiving Party without knowledge of or access to Confidential Information; or (e) approved by release by written authorisation of the Disclosing Party.
- 11.2. No Disclosure or Use. The Receiving Party shall use reasonable efforts to safeguard the confidentiality of the Confidential Information and shall not disclose or use the Confidential Information except for the purpose of performing its obligations or exercising its rights under this Agreement. For clarity, MPP shall have the right to share the reports and any other Confidential Information provided hereunder with the Funder and the WHO. If the Receiving Party is required by law, regulation or court order to disclose Confidential Information, then the Receiving Party may furnish this required Confidential Information, provided the Receiving Party has promptly notified the Disclosing Party and reasonably assisted the Disclosing Party in its efforts to seek and / or obtain a protective order or other remedy of the Disclosing Party’s election.
- 11.3. Survival. The obligations of non-disclosure and non-use shall survive termination or expiration of this Agreement. Receiving Party agrees to return or destroy all Confidential Information, as requested by the Disclosing Party, except that, subject to the terms and conditions herein, the Receiving Party may retain one copy of Confidential Information solely to evidence its compliance and those electronic files maintained for archival purposes.
- 11.4. Privacy Laws. SAHPRA, Project Lead and WHC shall comply with all privacy and data protection laws and regulations applicable to the subject matter of this Agreement, including, taking all appropriate action to protect the privacy and confidentiality of all persons appointed or employed as part of the Project. These Parties shall notify each other immediately (within 24 hours) in case of any issues regarding compliance with this Clause 11.4, and Project Lead shall notify MPP of any such issues.

## 12. Use of Documents

- 12.1. Use of reports. MPP has the right to use the contents contained in any document, including any SAHPRA Financial Reports, SAHPRA Annual Finance Audit Statements, WHC Financial Statements, and WITS Annual Finance Audit Statement under Clause 8 and Technical Reports under Clause 9, that it receives under this Agreement for any purpose related to the mRNA Technology Transfer Programme, unless as otherwise agreed between the relevant Parties.
- 12.2. Publications. MPP may freely publish, present, use or otherwise disseminate any documents or results arising out of the performance of this Agreement for its own purposes, provided that the publication, presentation or use does not disclose any Confidential Information of the other Parties. SAHPRA and WHC shall obtain the prior written consent of MPP prior to making any communications with respect to this Agreement and shall comply with any reasonable directions by MPP with respect to acknowledgement of MPP’s Funders on such communications.

## 13. Reports and Notices

- 13.1. All reports and notices under this Agreement shall be in writing, properly addressed as below or as otherwise provided in accordance herewith and shall be deemed to have been duly given or received upon the earlier of: (a) actual receipt, (b) the date of confirmed delivery according to the records of a commercially recognised express courier with tracking capabilities; or (c) the date of confirmed transmission if sent by email with confirmation of delivery.



If to MPP:  
Medicines Patent Pool Foundation  
Rue de Varembe 7  
1202 Geneva, Switzerland  
Attention: General Counsel  
Email: legal@medicinespatentpool.org

If to WHC:  
Supporting Health Initiatives, a Division of Wits  
Health Consortium (Pty) Ltd  
31 Princess of Wales Terrace,  
Parktown, Johannesburg, 2190  
Attention: Ms Robyn Hayes Badenhorst  
Email: rhayes@witshealth.co.za  
Legal: ceo@witshealth.co.za

If to Project Lead:  
Raj Long  
4 Drill Court  
Walmer England  
Attention: Raj Long  
Email: raj.long@gatesfoundation.org

If to SAHPRA:  
South African Health Products Regulatory Authority  
Second Floor, Building A, Loftus Park, 402  
Kirkness Street, Arcadia, Pretoria  
Attention : Dr Boitumelo Semete-Mokokotlela  
Email: Boitumelo.Semete@sahpra.org.za

#### 14. **Indemnity and Insurance**

- 14.1. Indemnification. A Party (“**Indemnifier**”) shall indemnify, hold harmless and defend the other Party, its affiliates, and their respective officers, directors, employees, independent contractors and agents (“**Indemnitee**”) from and against any and all claims, losses, damages, and / or liability of whatsoever kind or nature, as well as all costs and expenses, including reasonable attorneys’ fees and court costs (“**Losses**”) which arise or may arise at any time out of or relating to the Indemnifier’s and / or its independent contractor’s or agent’s performance or breach of this Agreement and / or any act or omission of negligence or willful misconduct by the Indemnifier or its independent contractor or agents; except to the extent of such Losses that are attributable solely to the Indemnitee’s breach of this Agreement, gross negligence or willful misconduct. The Indemnifier shall not settle or compromise any claim or allegation subject to indemnification hereunder in a manner that imposes any material obligation on, or makes any admission of fault by, Indemnitees. Indemnitees shall cooperate as reasonably requested, at the expense of the Indemnifier, in the defense of the action.
- 14.2. Insurance. SAHPRA and WHC shall continuously maintain at its own expense sufficient insurance levels throughout the term of this Agreement and beyond to ensure its obligations under this Agreement and shall provide evidence of adequate insurance coverage upon request.
- 14.3. Limitation of Liability. NO PARTY SHALL BE LIABLE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, INCIDENTAL, EXEMPLARY, OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR REVENUE) ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER THEY SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW, OF THE POSSIBILITY OF SUCH DAMAGES.

#### 15. **Termination**

- 15.1. Term. The term of this Agreement commences on the Effective Date and continues until the 31 January 2026, unless earlier terminated in accordance with this Clause 15.1.
- 15.2. Grant Reduction. In the event MPP reduces the funding for the Project, Project Lead and SAHPRA shall enter into good faith negotiations to determine if the Project can be completed as originally anticipated or its scope must be modified. In the event of insufficient funding and Project Lead and SAHPRA cannot agree to a modified Project and Budget, MPP may suspend this Agreement immediately. In the event of suspension of the Project, SAHPRA shall immediately cease incurring expenses and take every reasonable measure to cancel outstanding expenses. If funding is reduced to the extent that Project Lead, in consultation with SAHPRA, determines it is not practicable to continue this Project, MPP may terminate this Agreement effective immediately upon notice.
- 15.3. Termination for cause. MPP may terminate this Agreement, in whole or in part, at any time with immediate effect (or on such date that is set out in the notice of termination) by giving written notice to the Parties if:

- a) SAHPRA:
  - i) commits a breach of any clause of this Agreement that is:
    - A. not capable of being remedied; or
    - B. if capable of being remedied, fails to remedy such breach within 20 working days after receiving a written notice specifying the nature of the breach; or
  - ii) ceases to conduct its operations; or
  - iii) becomes unable to perform the Project; or
  - iv) engages in serious misconduct or fraud; or
- b) substitutes for persons cannot be agreed upon under Clauses 1.3 and 1.4, effective as of the date of such event.

In the event that either WHC or Project Lead commit a breach that is (a) not capable of being remedied or, if capable of being remedied, fails to remedy such breach within 20 working days after receiving written notice, or (b) ceases to conduct its operations, the non-breaching Parties shall find a mutually acceptable substitute to replace the breaching Party as a party under this Agreement. In the event a mutually acceptable substitute is not found within a reasonable time, the Agreement may be terminated.

15.4. Project Reports. Within 20 working days of the date of termination of this Agreement;

- a) SAHPRA shall deliver to Project Lead any due Technical Reports under Clause 9 (including any due Deliverables) but not yet provided to Project Lead, including any further information or documentation requested that was created in the performance of the Project. Within 5 working days of receipt of such technical reports, information, or documentation, Project Lead shall provide to MPP a copy of such technical reports, information, or documentation;
- b) SAHPRA shall deliver to Project Lead and WHC any due SAHPRA Financial Reports or SAHPRA Annual Financial Audit Statement under Clause 8 but not yet provided to Project Lead and WHC. Within 5 working days of receipt of a such financial reports and statements, WHC shall provide to MPP a copy of such financial reports and statements; and
- c) WHC shall deliver to MPP any due WHC Financial Statements or WITS Annual Finance Audit Statement under Clause 8 but not yet provided to MPP.

MPP may use the foregoing for any purpose in furtherance of its mission. If applicable, SAHPRA and WHC agree to cooperate with the other Parties in the transfer of the Project to another contractor.

15.5. Surviving Rights and Obligations. The termination or expiration of this Agreement does not relieve any Party of its rights and obligations that have previously accrued. Terms and conditions of this Agreement that by their nature prescribe continuing rights and obligations shall survive the termination or expiration of this Agreement.

15.6. Other Effects of Termination.

- a) Exit meeting. The Project Committee shall hold a final meeting as soon as reasonably practicable just before or following termination and shall be dissolved after all final reporting has been completed.
- b) Unspent funds. Upon termination of this Agreement, SAHPRA shall return all funding received from WHC under this Agreement which is unspent at the date of termination (after deduction of costs and non-cancellable commitments incurred prior to the date of termination). WHC shall return all remaining Funds received from MPP, including funds returned from SAHPRA under this Clause 15.6(b) to MPP.
- c) Post-exit reporting. In the event that the Agreement terminates for any reason (including expiry) and provided that SAHPRA continues to work on the Project, SAHPRA shall continue to provide Project Lead with an annual progress update report that covers the following:
  - i) state of the development and strengthening of SAHPRA's mRNA regulatory capacity; and
  - ii) the training of any human resources recruited by SAHPRA as part of the Project, including of any replacement of such personnel, and the mRNA-related regulatory work performed by such personnel.

Within 5 working days of receipt of such an annual progress update report under this Clause 15.6(c), Project Lead shall provide to MPP a copy of such report.

**16. Compliance with Law**

- 16.1. Mutual Representations and Warranties. Each Party represents and warrants that it shall comply with all applicable laws and regulations, including without limitation those governing conflict of interest and that it shall respect the human rights of its staff and adopt all necessary measures to combat sexual exploitation, abuse, and harassment, including implementing effective prevention, monitoring and response mechanisms. Each Party shall notify the other Parties immediately (within 24 hours) in case of any issues regarding compliance with the rules set out this Clause 16.1.
- 16.2. WHC, Project Lead and SAHPRA Representations and Warranties. WHC, Project Lead, and SAHPRA further represents and warrants that: (a) it has all necessary rights to perform its obligations under this Agreement; (b) that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any governmental department or agency; and (c) in the case of SAHPRA, all personnel working on the Project, including Key Personnel, have met all legal and organisational requirements required to perform the work anticipated hereunder with the appropriate level of skill required therefor.
- 16.3. Disclaimer. EXCEPT AS PROVIDED IN CLAUSES 16.1 AND 16.2, NO PARTY MAKES ANY AND EACH EXPRESSLY DISCLAIMS ALL REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, REGARDING ITS PERFORMANCE UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION THE MARKETABILITY, USE OR FITNESS OF THE DELIVERABLES OR RESULTS DEVELOPED HEREUNDER FOR ANY PARTICULAR PURPOSE.

**17. Dispute Resolution**

- 17.1. Dispute. The Parties wish to facilitate the resolution of any dispute arising out of or relating to this Agreement including but not limited to the breach, termination, interpretation or validity thereof (a "**Dispute**") in an expedient manner by mutual cooperation and agree to follow the procedures set forth in this Clause 17 to resolve any such Dispute.
- 17.2. Escalation. If a Dispute arises between any of the Parties and cannot be resolved between those Parties' respective operational teams, and in the case of Project Lead, Project Lead herself, within 20 working days of written notice by one Party to another, such Dispute shall be referred in writing to the Parties' respective executive officers or their designees ("**Designated Officers**") for attempted resolution by good faith negotiations which shall take place within 20 working days after such referral (or within such other time period as may be agreed by the Parties in writing). For the avoidance of doubt, Project Lead shall also be the Designated Officer.
- 17.3. Arbitration. If a Dispute remains unresolved 20 working days (or such other time period as may be agreed by the Parties in writing) after referral to the Parties' Designated Officers pursuant to Clause 17.2, any Party may refer the Dispute for resolution by final and binding arbitration conducted in accordance with the WIPO Arbitration Rules. The arbitration shall be conducted in English and the arbitral tribunal shall consist of three arbitrators. The place of arbitration shall be Geneva, Switzerland. Parties do not object to arbitration proceedings being held online.
- 17.4. Injunctive relief. Notwithstanding the foregoing, nothing in this Clause 17 shall be construed as precluding a Party from bringing an action in court for interim injunctive relief or other interim equitable relief.

**18. Miscellaneous**

- 18.1. Amendment. The Parties may only amend or vary this Agreement in writing and signed by each of the Parties.
- 18.2. Assignment. No Party may assign or transfer this Agreement to another without the prior written consent of the other Parties. Such successor shall expressly assume in writing the obligation of this Agreement. Any other assignment or transfer shall be void.
- 18.3. Entire Agreement. This Agreement, including any Annexure, constitutes the entire agreement between the Parties with respect to the subject matter and supersedes all prior communications, agreements or understandings, written or oral regarding such subject matter.

- 18.4. Relationship. Nothing in this Agreement shall be interpreted as placing the Parties in an employment, partnership, joint venture or agency relationship and no Party shall have the right or authority to obligate or bind any other Party on its behalf.
- 18.5. Governing Law. This Agreement shall be governed by the laws of Switzerland, without giving effect to any choice-of-law provision that would require the application of the laws of a different jurisdiction. This Agreement shall be construed in the English language.
- 18.6. Waivers. A delay or failure to assert a right or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver or excuse a similar or subsequent failure to perform any such term or condition. A valid waiver shall be executed in writing and signed by the Party granting the waiver.
- 18.7. Severability. In the event that any portion of this Agreement is or is held by any court or tribunal of competent jurisdiction to be illegal, void, unenforceable or ineffective, the remaining portions hereof shall remain in full force and effect. If any of the terms or provisions of this Agreement conflict with any applicable statute or rule of law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to the minimum extent necessary to procure conformity with such statute or rule of law.
- 18.8. Use of Names. No Party shall use the name of any other Party, or Funder or of any staff member, employee or student of any other Party or any adaptation, acronym, or name by which any other Party is commonly known, in any advertising or sales literature or any publicity without the prior written approval of the other Party or individual whose name is to be used.
- 18.9. Execution. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. For the convenience of the Parties, an executed copy of this Agreement may be transmitted by email in portable document format (PDF), and such .pdf file shall be deemed equivalent to an original.

IN WITNESS WHEREOF the Parties, through their duly authorised representatives, have executed this Agreement.

*(Signature page on the next page)*

Signed on behalf of  
**Medicines Patent Pool**

DocuSigned by:

*Charles Gore*

10/26/2023

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Signature

Date

Print Name: Charles Gore

Title: Executive Director

Signed on behalf of  
**Wits Health Consortium (Pty) Ltd**

DocuSigned by:

*Alfred Farrell*

11/16/2023

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Signature

Date

Print Name: Alfred Farrell

Title: Chief Executive Officer

Signed by  
**Raj Long**

DocuSigned by:

*Raj Long*

11/6/2023

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Signature

Date

Print Name: Raj Long

Title: Project Lead

Signed on behalf of  
**South African Health Products Regulatory Authority**

DocuSigned by:

*Boitumelo Semete*

10/28/2023

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Signature

Date

Print Name: Boitumelo Semete

Title: Chief Executive Officer