MEMORANDUM OF UNDERSTANDING BETWEEN THE WORLD HEALTH ORGANIZATION AND THE MEDICINES PATENT POOL FOUNDATION

This Memorandum of Understanding ("**MOU**") is made as of 1 January 2024 by and between the World Health Organization ("**WHO**"), a specialised agency of the United Nations responsible for international public health, whose headquarters is located at Avenue Appia 20, 1211, Geneva, Switzerland, and Medicines Patent Pool Foundation ("**MPP**"), a non-profit foundation organised under the laws of Switzerland, whose business headquarters is located at Rue de Varembe 7, Geneva 1202, Switzerland, together the "Parties," individually, a "Party".

Background:

WHO is the directing and coordinating authority for health-related work with an international dimension; it is the lead agency for health questions at the global level; it develops health research programmes; it defines health standards and criteria; it formulates evidence-based policy options; it provides technical support to Member States in the area of health, and it monitors and assesses health trends. WHO acts in conjunction with its regional and country offices and Member States as needed to accomplish this health-related mission.

MPP is a non-profit foundation with a mission to improve the health of people living in low- and middle-income countries ("**LMICs**") by increasing access to quality, safe, efficacious and affordable medicines and medical technologies by facilitating access to intellectual property to allow for the rapid development and manufacturing of these medicines and technologies. MPP's mandate also covers COVID-19 technologies, with a particular focus on promoting technology transfer for COVID-19 vaccines.

WHO and MPP, along with Afrigen Biologics (PTY) Limited ("**Afrigen**"), the South African Medical Research Council ("**SAMRC**") and the Biologicals and Vaccines Institute of Southern Africa ("**Biovac**") (together the "**SA Consortium**"), desire to address the inequalities in access to vaccines in LMICs that emerged during the COVID-19 pandemic and to strengthen regional health security and respond more equitably to future pandemics.

WHO and MPP are co-conveners of the mRNA Technology Transfer Programme ("**Programme**") which aims to create and enhance sustainable mRNA vaccine manufacturing capacity and to develop skilled human capital in LMICs where mRNA vaccine manufacturing capacity is limited or non-existent. The Programme is based around the SA Consortium (responsible for a technology platform development and technology transfer), and 14 partners in LMICs ("**Partners**"), who have expressed an interest to WHO in participating in the Programme, being BioVax, Bio-Manguinhos, Biofarma, BiologicalE, BioGeneric Pharma, Biovaccines Nigeria, Darnitsa, Incepta Vaccine, Institut Pasteur de Dakar, Institut Pasteur de Tunis, Institut Torlak, National Institute of Health Islamabad Pakistan, Polyvac, Sinergium Biotech.

As part of the Programme, Afrigen will develop a mRNA technology platform (using COVID-19 as proof of concept) and transfer it through the provision of "technology transfer package(s)",

comprising of technical information, technical assistance, and materials, among other things, to the 14 Partners and Biovac, thus enabling them to develop, produce and sell products commercially.

Biovac will receive the mRNA technology platform from Afrigen and will scale-up and validate the process to the intended commercial scale. SAMRC will develop a pipeline of mRNA-based vaccine candidates for diseases relevant for LMICs in collaboration with other research institutions and conduct early development research on a 2nd generation mRNA technology platform that aims to improve thermostability, reduce the cost of goods, and address any freedom to operate barriers.

On 29 July 2021, WHO, MPP, Afrigen, SAMRC, and Biovac entered into a letter of intent, which sets out the framework for their collaboration on the Programme. On 7 February 2022 and 4 October 2022, WHO and MPP entered into Grant Letter of Agreements ("**GLOA**") in which WHO agreed to provide MPP with EUR1,130,072 and EUR1,000,000, respectively, to support MPP in the implementation of the Programme. At the time of this MOU, WHO and MPP are finalising another GLOA in which WHO is expected to provide MPP with USD 5,231,000 for the same purpose.

To that end, the Parties have agreed upon a further framework of collaboration (the "**Collaboration**") between them as follows:

(1) Description of the Collaboration. The Parties wish to perform the following activities to achieve the abovementioned objective of this Collaboration:

a) **Responsibilities of the Parties**. The Parties will be jointly responsible for the performance of the activities set out in this section, which will entail the Parties engaging in routine communications with each other as required for their performance. To the extent, a Party performs an activity, such performance will not relieve the other Party from its performance of that activity, unless otherwise agreed between the Parties.

i. Programme coordination

A. Review, coordinate, monitor and lead the strategy for the implementation of the activities of the Programme, including the development and transfer of the mRNA technology platform.

B. Engage with private and public organisations implementing programmes similar to the Programme to promote collaboration and minimise duplication.

C. Maintain a risk register for the Programme to monitor and assess the impact of any potential and actual risks, and implement risk prevention and mitigation strategies.

ii. Technical

A. Select and define the mRNA technology platform to be developed and transferred under the Programme.

B. Provide ongoing review and guidance on the technical strategy for the development and transfer of the mRNA technology platform to the Partners.

C. Review the progress and provide technical support in the development and transfer of the mRNA technology platform to the Partners.

D. Coordinate and convene meetings with technical experts (e.g., WHO Scientific and Technical Review Committee - STeRCo, MPP mRNA Scientific Advisory Committee - mSAC, WHO Product Development and Vaccine Advisory Committee

- PDVAC) to advise the SA Consortium and the Programme leadership on research strategies and the selection of disease targets for the Programme.

E. Provide guidance and support to the SA Consortium and Partners on emerging practices and trends in the development and manufacture of mRNA-based vaccine products.

F. Facilitate and support the coordination and collaboration among Partners in performing R&D activities related to the development of mRNA-based vaccine candidates by:

   I. summarising publicly available information on new mRNA R&D and manufacturing initiatives in Partner countries; and

   II. assisting in the provision of hands-on training from Afrigen and other relevant training centres to Partners to perform R&D and manufacture mRNA-based vaccines.

G. Provide scientific and technical guidance and support to the SA Consortium for the development and manufacture of mRNA-based vaccine candidates for disease areas other than COVID-19 (e.g., tuberculosis and HIV). .

iii. Resources mobilisation and management

A. Evaluate the financial resources required by the SA Consortium, Partners, and other relevant stakeholders, as well as each Party, to perform their activities under the Programme.

B. Evaluate new activities, including related budgets, to be performed by the SA Consortium, Partners, and other relevant stakeholders, as well as each Party, for inclusion as part of the Programme.

C. Engage with funders to ensure the availability of resources for the SA Consortium (from platform development up to Phase III using COVID-19 as the proof of concept and 2nd generation early development), Partners (for training, equipment, raw materials, sites assessment) and other relevant stakeholders (for regulatory strengthening) to perform their activities under the Programme.

D. Report to funders on the expenditure and progress on the implementation of the activities of the Programme by SA Consortium, Partners, and other relevant stakeholders, as well as each Party.

iv. Training

A. Assess the biomanufacturing training needs of the personnel of the SA Consortium and Partners and, where possible, support their participation in relevant training (e.g., GxP, mRNA technology and associated applications, regulatory processes).

v. Possible future collaboration

A. Examine the feasibility of using the Programme as a template for the technology transfer of other platforms such as for subunit vaccines or monoclonal antibodies and, if feasible and requested by Member States, establish programmes to do so.

b) **Responsibilities of WHO**. WHO will be solely responsible for the performance of the activities set out in this section. WHO will keep MPP continuously informed on the status and progress of the performance of these activities. MPP may provide comments to WHO in relation to the performance of these activities, and WHO will give good faith consideration to any such comments received from MPP.

i. Programme coordination

A. Define the process and criteria for receiving and evaluating requests from institutions and/or Member States and their selection to become partners of the Programme.

B. Convene advisory bodies and engage with stakeholders to advise on the implementation of the Programme, and document and analyse their suggestions (e.g., Member States, WHO regional forums).

C. Provide guidance to Partners and their governments on areas relevant for the development of an ecosystem suitable for the sustainable manufacturing of mRNA-based vaccines, including in the context of pandemic preparedness and response.

D. Convene and support the establishment of connections between Partners and investors to promote innovation in funding mechanisms for mRNA technology initiatives in LMICs.

E. Ensure the Programme is aligned and compatible with other relevant WHO initiatives (e.g., the global biomanufacturing training initiative).

ii. Technical

A. Provide guidance to the Partners on infrastructure investments necessary for the implementation of a mRNA-based vaccine manufacturing platform (e.g. mRNA R&D, pilot, commercial) and associated funding requirements.

B. Identify potential targets and product characteristics for new mRNA-based vaccines in LMICs and emerging mRNA-related technologies (e.g., innovative processes, new raw materials, new equipment).

C. Convene regional R&D consultations with WHO representatives, Partners, and other relevant stakeholders on the R&D of mRNA-based vaccines in LMICs.

D. Convene bi-annual R&D meetings with the SA Consortium and Partners to review and harmonise the mRNA-based vaccine pipeline, and support prioritisation of disease targets.

iii. Training

A. Support, as appropriate, relevant training on mRNA-based vaccine registration requirements and processes for the SA Consortium and Partners.

c) **Responsibilities of MPP**. MPP will be solely responsible for the performance of the activities set out in this section. MPP will keep WHO continuously informed on the status and progress of the performance of these activities. WHO may provide comments to MPP in relation to the performance of these activities, and MPP will give good faith consideration to any such comments received from WHO.

i. **Technical**

A. Coordinate the technology transfer of the mRNA technology platform to the Partners.

B. Support the SA Consortium in the development of the mRNA technology platform and the demonstration of its safety, immunogenicity, and efficacy.

C. Support the SA Consortium in research activities related to the improvement of the manufacturing process for mRNA-based vaccines and to address identified issues or gaps (e.g., freedom to operate, cost of goods, thermostability).

D. Support the SA Consortium in the preparation and provision of the technology transfer package(s) to the Partners.

E. Conduct site assessments at the Partners' facilities to assess their capabilities and identify actions and deliverables for them to successfully receive and implement the mRNA technology platform.

F. Support the Partners in defining the technology transfer strategy, preparing the technology transfer readiness and execution plans and provide technical support during the technology transfer to the Partners, Afrigen and Biovac.

G. Support the SA Consortium and any other relevant parties in the procurement of reference products for them to conduct pre-clinical and clinical studies to demonstrate the safety and efficacy of the mRNA technology platform.

ii. **Resources mobilisation and management**

A. Organise quarterly reporting (at Funders Forum meetings) and provide written monthly updates to mRNA Programme funders.

B. Manage and monitor the activities and expenditures of the SA Consortium and Partners to ensure good compliance.

C. Support the participation of SA Consortium and the Partners in relevant training based on identified training needs and funds availability.

D. Facilitate access to technical support to national regulatory authorities to enable the regulatory assessment of mRNA-based vaccine production facilities, products, and product dossiers.

iii. **Legal**

A. Establish the legal framework for the Programme by negotiating and entering into any necessary contractual agreements with the SA Consortium, Partners, WHO and other relevant stakeholders.

iv. **Intellectual property**

A. Provide IP analysis and commission freedom to operate assessments for the Partners, as necessary.

B. Generate and provide IP landscape analysis related to mRNA-based vaccines and technologies for COVID-19 and other disease targets relevant for LMICs to the SA Consortium and Partners.

C. Coordinate and organise IP trainings for the SA Consortium and Partners, as necessary.

v. **Communication/advocacy**

A. Prepare the communication materials relating to the Programme (e.g., presentations, printed materials, Q&A).

B. Collect stories and video that illustrate the progress of the Programme and engage with media and external stakeholders on the progress.

C. Develop, maintain and update, as required, the webpages on the Programme on the MPP website.

D. Develop and implement a communications plan to maintain engagement by stakeholders and promote the work of the Programme and Partners.

E. Organise and convene events to promote the Programme and to engage with stakeholders, including quarterly meetings with civil society organisations and funders.

F. In coordination with WHO, advocate for local investments and support for addressing challenges in the implementation of the Programme.

(2) Implementation, Financial Obligations, and Fundraising.

a) Implementation of any of the activities outlined in this MOU will be subject to the availability of sufficient financial and human resources for that purpose, as well as each Party's programme of work, priority activities, policies, rules and regulations, as well as its administrative procedures and practices.

b) There is no transfer of funds between the Parties under this MOU, and any transfer of funds for the performance of any activity set out in this MOU would be subject to separate agreement.

c) No Party will engage in fundraising with third parties for activities to be carried out pursuant to this MOU in the name of, or on behalf of, the other Party, without the prior written approval of the other Party.

d) Each Party shall bear the costs and expenses attendant upon its participation in the activities under this MOU or resulting from this MOU.

e) This MOU represents no commitment on the part of any Party concerning the financing of any particular activity.

(3) Press Release and Other Communications.

a) The signature of the present MOU may be announced through a press release agreed to by the Parties.

b) Subject to the provisions of Section 7 below, each Party may acknowledge the existence of this MOU to the public, as well as to the extent possible, general information with respect to the collaborative activities contemplated herein. Such disclosure will be made in accordance with the disclosing Party's respective disclosure policies, provided always that any such disclosure will be consistent with the terms of this MOU.

c) Each Party may publish this MOU on its website, provided that the context in which each Party intends to do so will be subject to the advance written agreement of the other Party (agreement not to be unreasonably withheld), and except as explicitly provided herein, this MOU and any subsequent agreements and/or any individual clauses contained therein will not be publicly disclosed or made available without the prior written agreement of both Parties.

d) The Parties agree to designate a point of contact in their organisations to coordinate communications and facilitate the monitoring of the activities under this MOU. The points of contact for each Party are as set out below. Any changes to the points of contact referred to below shall be notified to the other Party in writing (email is acceptable) without delay.

MPP	Ike James Head of Technology Transfer Email: ijames@medicinespatentpool.org
WHO	Claudia Nannei Manager and Policy and Partner Engagement Lead, mRNA TT programme Email: nanneic@who.int

(4) Confidentiality.

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

b) The Parties shall hold in the strictest confidence any of the other Party's Confidential Information; and shall not distribute, disclose or convey Confidential Information to any third party and shall not make use of any Confidential Information for its own benefit or for the benefit of any third party. Notwithstanding the foregoing, the Parties shall not be in violation of this subsection in the event that a Party is legally compelled to disclose any of the Confidential Information.

c) Any legally-binding documentation entered into by the Parties in relation to this MOU and the Collaboration shall contain relevant clauses referring to or incorporating the provisions of this Section 4 relating to the treatment of Confidential Information.

d) The obligations of this Section 4 shall continue for a period of [five (5) years] after the termination of this MOU.

(5) Intellectual Property Rights. Each Party maintains the intellectual property it owns. In the event of joint implementation of activities pursuant to this MOU which result in the development of intellectual property rights, the provisions regarding such intellectual property rights will be determined by separate agreement between the Parties prior to the dissemination of such intellectual property.

(6) Status of MOU. This MOU is non-legally binding and represents the framework for future discussions between and activities by the Parties in relation to the Collaboration. The commencement of any activities contemplated by this MOU will be subject to an agreement and execution of legally-binding documentation.

(7) Official Emblems and Logos. No Party will use the name, emblem, logo, or trademark of the other Parties, their subsidiary bodies, or affiliates, in any way, including in any publication or public document, without the prior written approval of the other Party concerned.

(8) Responsibility.

a) Failure to respect an obligation under this MOU, or fulfilment or non-fulfilment under this MOU, shall entail no responsibility, and specifically no financial responsibility, of either Party towards the other Party.

b) Each Party bears sole responsibility for the manner in which it undertakes its share of activities under this MOU, for its acts or omissions with respect to this MOU, and for its implementation and/or any subsequent arrangement.

c) No Party shall bear responsibility for losses, accidents, damage or injury suffered or caused by the other Party, or by their staff or contractors in relation to or resulting from cooperation and collaboration under this MOU.

(9) Effective Date, Term and Termination.

a) This MOU shall become effective on the date of last signature and continues for [five (5) years]. It may be modified by mutual written consent of the Parties. A Party may terminate this MOU subject to three (3) months' advance written notice to the other Party. Any such termination will be without prejudice to the orderly completion of any ongoing activity pursuant to this MOU as of the time of such notice of termination.

b) The MOU can be renewed by written amendment signed by both Parties, such amendment setting forth the terms and conditions of the renewal.

(10) Dispute Resolution and Privileges and Immunities.

a) In the event of a dispute, controversy or claim arising out of or relating to this MOU, the Parties will use their best efforts to promptly settle such dispute through direct negotiation. Any dispute that is not settled within sixty (60) days from the date either Party has notified the other Party of

the nature of the dispute and of the measures that should be taken to rectify it will be resolved through consultation between the Heads of the Parties.

b) Nothing contained herein will be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national or international law, and/or as submitting WHO to any national court jurisdiction.

THE WORLD HEALTH ORGANIZATION

BY: _____

Name: Dr Yukiko Nakatani

Title: Assistant Director-General

Access to Medicines and Health Products

Date: 01 JAN 2024

THE MEDICINES PATENT POOL FOUNDATION

BY: _____

Name: Charles Gore

Title: Executive Director

Date: January 1 2024