

**LETTER OF INTENT
BETWEEN THE WORLD HEALTH ORGANIZATION, THE MEDICINES PATENT
POOL FOUNDATION, AFRIGEN BIOLOGICS (PTY) LIMITED, THE BIOLOGICALS
AND VACCINES INSTITUTE OF SOUTH AFRICA, THE SOUTH AFRICAN
MEDICAL RESEARCH COUNCIL,
AND THE AFRICAN CENTRES FOR DISEASE CONTROL AND PREVENTION**

This Letter of Intent ("LOI") is made as of 29 July 2021 by and between the World Health Organization ("WHO"), a specialized agency of the United Nations responsible for international public health, whose headquarters is located at Avenue Appia 20, 1211, Geneva, Switzerland, 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, Afrigen Biologics (PTY) Limited ("Afrigen"), a with registration number 2014/135714/07, a company registered in South Africa with registered office at Unit 5&6 Kestrel Park, Longclaw Drive, Montague Gardens, 7441, Cape Town, South Africa, legally represented by Prof Aletta Petronella Susarah Terblanche the signatory hereto, The Biologicals and Vaccines Institute of Southern Africa ("Biovac"), a company duly registered under the laws of the Republic of South Africa with Registration number: 1998/011727/07 whose registered address being, 15 Alexandra Road, Pinelands, 7405, Cape Town, South Africa, the South African Medical Research Council ("SAMRC") a National Public Entity in terms of Schedule 3 of the Public Finance Management Act 1 of 1999 and statutory science council established in terms of Section 2 of the Medical Research Council Act 58 of 1991 with its principal place of business situated at: Francie Van Zyl Drive, Parow Cape Town represented herein by Professor Glenda Gray in her capacity as President, and the Africa Centres for Disease Control and Prevention ("Africa CDC"), together the "Parties," individually, a "Party":

Background:

Despite the scientific advances that have allowed safe and effective vaccines for Covid-19 to be developed and deployed at unprecedented speed, the Covid-19 pandemic has also laid bare the global inequities in access to these vaccines and other critical technologies. Billions of doses of Covid-19 vaccines have been administered globally to date, but only a small fraction of those have been in low-income countries, with the African continent left in particular neglect. One factor contributing to this inequity is the global imbalance of manufacturing capacity, with the bulk of Covid-19 vaccine manufacturing capacity located in high- and upper-middle income countries. In order to strengthen regional health security and respond more equitably to the current Covid-19 pandemic and future pandemics, there is an urgent need to establish greater and more diversified vaccine manufacturing capability and capacity.

WHO is the directing and coordinating authority for health-related work with an international dimension; that it is the lead agency for health questions at the global level; that it develops health research programmes; that it defines health standards and criteria; that it

formulates evidence-based policy options; that it provides technical support to Member States in the area of health, and that it monitors and assesses health trends. WHO will act in conjunction with its regional offices (including WHO AFRO) and Member States as needed in the accomplishment of 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 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 recently expanded its mandate to cover Covid-19 technologies, with a particular focus on promoting technology transfer for Covid-19 vaccines.

Afrigen is a biotechnology company incorporated in South Africa. Afrigen established the first adjuvant formulation laboratory in Africa and has a pipeline of vaccines in development. Afrigen has built strong research and development partnerships with leading Universities in SA and Africa. It has recently completed a facility suitable for the establishment of a fully integrated mRNA pilot scale production, formulation and fill finish platform. Afrigen and a technical scientific, quality control and quality assurance and regulatory teams that is geared to provide a platform for the implementation of an mRNA Hub for Africa. SA Afrigen will lead phase 1 of the implementation of the first WHO mRNA Hub in Africa.

Biovac is a South African specialist vaccines company that was established to revive local human vaccine production in Southern Africa. Alongside the development of bacterial vaccine technologies, the company has built modern facilities and secured high profile technology transfers from international vaccine companies. The company also sources and supplies a comprehensive range of vaccines required by the South African government including paediatric and COVID19 vaccines, across South Africa and into neighbouring countries.

SAMRC is a statutory entity established in 1969 with a mandate to improve the health of the country's population, through research, development and technology transfer. The SAMRC conducts and supports research across a broad range of disciplines and health priority areas, including but not limited to tuberculosis, HIV/AIDS, COVID-19 and other communicable diseases, cardiovascular and other non-communicable diseases, gender and health, health systems, and alcohol and other drug abuse. The SAMRC has decades of experience in managing large research consortia and local and international funding programs, in both the research and innovation domains. The SAMRC is leading South Africa's research and innovation response to COVID by actively funding, conducting and facilitating research and development and is an ideal implementing partner for driving product and clinical development.

Africa CDC is a specialized institution of the African Union charged with the responsibility of promoting health and prevention of diseases in Africa.

The Parties share an interest in building a sustainable mechanism that will increase vaccine manufacturing capacity and capability in Africa and elsewhere in low- and middle-income countries, through the establishment of a Covid-19 technology transfer hub.

To that end, the Parties have agreed upon a framework of collaboration (the “Collaboration”) as follows:

(1) Description of the Collaboration. The Parties wish to accomplish the following objectives through this Collaboration:

- a) Identify suitable platform technology(ies) that will form the basis of the technology transfer hub and enter into appropriate agreements to make such technology(ies) available to the hub and its recipients.
- b) Establish a multilateral training and technology transfer hub that would include elements of technology demonstration and technology scale-up, initially at Afrigen, for Covid-19 vaccines and routine biologics;
- c) Transfer the technology to recipients, initially to Biovac, for the manufacturing and commercialization of Covid-19 and other vaccine candidate(s);
- d) Secure sustainable funding to establish the hub and support pre-clinical and clinical studies, manufacturing support.
- e) Create a platform for innovation in vaccine discovery, development, testing and manufacturing in partnership with leading universities and research institutions in Africa.

(2) Responsibilities of the Parties

a) Responsibilities of WHO

- i. Coordinate and lead the Collaboration and monitor the implementation of its activities;
- ii. In consultation with MPP, engage with potential technology donors; evaluate the scientific and public health value of the potential technologies; identify lead candidates through an independent committee assessment;
- iii. Assemble teams of experts to support technology transfer to Afrigen and subsequently to Biovac and other recipients;
- iv. Facilitate the strengthening of the regulatory workforce in South Africa and other target countries;
- v. As required, provide support in developing clinical protocol templates for use by recipients and coordinate independent pre-clinical assessments and other normative studies;

- vi. Assist in seeking and securing funding to establish the hub and fund its activities.

b) Responsibilities of MPP

- i. Provide IP analysis and commission freedom to operate assessments, as necessary;
- ii. In consultation with WHO, define the terms and conditions under which the donor technology will be made available to the Collaboration; as well the terms and conditions under which such technology will be made available to Afrigen (and future hubs) and Biovac (and future recipients);
- iii. Negotiate and draft appropriate binding agreements with technology donor(s); Afrigen (and future hubs) and Biovac (and future recipients) that fulfil the public health objectives of the Collaboration;
- iv. Manage and monitor the activities of hubs and recipients to ensure good compliance;
- v. Jointly with WHO, establish a process by which additional technology recipients will be identified and selected;
- vi. In consultation with WHO, design and draft any further governance or technology transfer documents as necessary to fulfil the objectives of the Collaboration.

c) Responsibilities of Afrigen

- i. Establish all necessary infrastructure and personnel to ensure proper functioning of the hub;
- ii. Enter into a binding arrangement with MPP governing the terms and conditions under which it will receive the technology(ies) from the technology donor(s);
- iii. With the support of WHO, establish a training programme to transfer technology and provide regular training programmes for additional recipients as requested by WHO;
- iv. Enter into a binding arrangement with MPP governing the terms and conditions under which it will transfer technology to Biovac and subsequent recipients;
- v. Participate in the creation of a sustainable innovation platform for future vaccine development and manufacturing.

d) Responsibilities of Biovac

- i. Establish all necessary infrastructure and personnel for effective and efficient production of Covid-19 vaccines;

- ii. Enter into a binding arrangement with MPP governing the terms and conditions under which it will receive the technology transfer from Afrigen, develop, test, register and commercialize Covid-19 vaccines;
- iii. Enter into appropriate arrangements to ensure appropriate access of its Covid-19 vaccines to other African countries and UN agencies.
- iv. Apply for WHO Pre-Qualification.

e) Responsibilities of SAMRC

- i. In consultation with WHO, provide necessary expertise to support technology transfer and absorption;
- ii. To project manage and have fiduciary and local IP oversight for Objective 3. (attached);
- iii. To enter into the necessary sub-agreements with collaborators, investigators and research entities to fulfil its mandate
- iv. To oversee the implementation/design of clinical trial studies;
- v. In collaboration with other bodies of the South African government, seek to secure funding to ensure the development of additional vaccine candidates to potentially secure the long-term sustainability of Afrigen as a technology transfer hub and Biovac as a manufacturing facility.

f) Responsibilities of Africa CDC

- i. To collaborate with the Parties and provide expertise as needed to advance the Collaboration.

(3) Implementation, Financial Obligations, and Fundraising

- a) Implementation of any of the activities outlined in this LOI 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) No transfer of funds between the Parties is envisioned in connection with this LOI, and any such transfer of funds 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 LOI 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 LOI or resulting from this LOI.
- e) This LOI represents no commitment on the part of any Party concerning the financing of any particular activity.

(4) Press Release and Other Communications.

- a) The signature of the present LOI may be announced through a press release agreed to by the Parties.
- b) Subject to the provisions of Section 8 below, each Party may acknowledge the existence of this LOI 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 LOI.
- c) Each Party may publish this LOI 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 LOI 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) All written communications exchanged under this LOI will be directed to the signatories of the present document

(5) Confidentiality.

- a) During the term of this LOI, a Party may make available to certain other Party(ies) Confidential Information (as hereinafter defined), or certain Party(ies) may otherwise learn of Confidential Information belonging to another 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 LOI or any other obligation of one Party to the other, or (iii) which was rightfully known to a Party prior to entering into this LOI.

- b) The Parties shall hold in strictest confidence any of the other Party(ies)'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. The foregoing notwithstanding, 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 LOI and the Collaboration shall contain relevant clauses referring to or incorporating the provisions of this Section 5 relating to the treatment of Confidential Information.
- d) The obligations of this Section 5 shall continue for a period of five (5) years after the termination of this LOI.

(6) Intellectual Property Rights

Each Party maintains the intellectual property it owns. In the event of joint implementation of activities pursuant to this LOI which result in the development of intellectual property rights, the provisions regarding such intellectual property rights will be determined by separate agreement among the Party or Parties concerned prior to the dissemination of such intellectual property.

(7) Status of LOI. This LOI is non-legally binding and represents the framework for future discussions between the Parties in relation to the Collaboration. The commencement of certain activities contemplated by this LOI will be subject to the agreement and execution of legally-binding documentation between the appropriate Parties. The Collaboration envisaged pursuant to this LOI does not imply WHO endorsement of any of the products or services of Afrigen Biologics or the Biologicals and Vaccines Institute of Southern Africa, nor does it preclude WHO from engaging with other stakeholders in relation to the subject matter of this LOI.

(8) 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.

(9) Responsibility

- a) Failure to respect an obligation under this LOI, or fulfilment or non-fulfilment under this LOI, shall entail no responsibility, and specifically no financial responsibility, of either Party towards any of the Party(ies).
- b) Each Party bears sole responsibility for the manner in which it undertakes its share of activities under this LOI, for its acts or omissions with respect to this LOI, and for its implementation and/or any subsequent arrangement. No Party shall bear responsibility for losses, accidents, damage or injury suffered or caused by the any of the Party(ies), or by their staff or contractors in relation to or resulting from cooperation and collaboration under this LOI.

(10) Effective Date, Term and Termination.

- a) This LOI 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. Any Party may terminate this LOI subject to three (3) months' advance written notice to the other Parties. Any such termination will be without prejudice to the orderly completion of any ongoing activity pursuant to this LOI as of the time of such notice of termination.
- b) The memorandum of understanding can be renewed by written amendment signed by both Parties, such amendment setting forth the terms and conditions of the renewal.

(11) Dispute Resolution and Privileges and Immunities.

- a) In the event of a dispute, controversy or claim arising out of or relating to this LOI, 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

DocuSigned by:
BY: Soumya Swaminathan
C761DA29C9C9463...

Name: Soumya Swaminathan

Title: Chief Scientist

Date: 30/07/2021

**THE MEDICINES PATENT POOL
FOUNDATION**

DocuSigned by:
BY: Charles Gore
4713D0F59C13482...

Name: Charles Gore

Title: Executive Director

Date: 29/07/2021

AFRIGEN BIOLOGICS (PTY) LTD

DocuSigned by:
BY: Petro Terblanche
3DDA01FF5FB3409...

Name: Petro Terblanche

Title: Managing Director

Date: 29/07/2021

**THE BIOLOGICALS AND VACCINE
INSTITUTE OF SOUTH AFRICA**

DocuSigned by:
BY: Morena Makhoana
879E633E5DFF46F...

Name: Morena Makhoana

Title: Chief Executive Officer

Date: 30/07/2021

**THE SOUTH AFRICAN MEDICAL RESEARCH
COUNCIL**


Glenda Gray
30/07/2021 13:33:11 (UTC+02:00)
Signed by Glenda Gray,
glenda.gray@mrc.ac.za
BY: _____
SIGNFLOW.COM

Name: Glenda Gray

Title: President and Chief Executive Officer

Date:

**THE AFRICAN CENTRES FOR DISEASE
CONTROL AND PREVENTION**

BY: Mungany

Name: John N. Nkengasong

Title: Director

Date: 30/7/2021