Execution version

DATED ___ APRIL 2021

JANSSEN PHARMACEUTICA NV

-and-

GOVERNMENT OF THE REPUBLIC OF SOUTH AFRICA ACTING THROUGH ITS NATIONAL DEPARTMENT OF HEALTH (THE "GOVERNMENT PURCHASER")

ADVANCE PURCHASE AGREEMENT

FOR SARS-CoV-2/COVID-19 VACCINE

(ADDITIONAL DOSES)

EMEA: 1663640-3

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THIS AGREEMENT is made as of ___ April 2021 ("**Effective Date**")

BETWEEN

1. **JANSSEN PHARMACEUTICA NV**, incorporated in Belgium, with company number 0403834160 whose registered office is at 30 Turnhoutseweg, B-2340 Beerse ("**Janssen**"); and

2. The Government of the Republic of South Africa, acting through its National Department of Health ("**Government Purchaser**"),

together the "**Parties**" and each a "**Party**".

WHEREAS:

A. The world is experiencing an emergency healthcare crisis from SARS-CoV-2/COVID-19.

B. The Johnson & Johnson group of companies, to which Janssen belongs, is developing the Vaccine Candidate (as defined below) through its affiliated company Janssen Pharmaceuticals, Inc., in response to the current SARS-CoV-2/COVID-19 pandemic, leveraging its proprietary AdVac® and high yielding manufacturing platforms, as well as its experience and capabilities gained from the development of its Ebola vaccine and investigational HIV, RSV and Zika vaccine candidates, with the aim of making available a safe and efficacious vaccine in 2021.

C. In response to the current COVID-19 pandemic and in view of the medical urgency, Janssen, together with its Affiliates, is currently executing an accelerated clinical development plan for the Vaccine Candidate, initiating multiple large multi-country studies within highly compressed timelines, based on the outcomes of multiple pre-clinical studies and initial clinical studies performed world-wide.

D. In parallel, and in an effort to ensure accelerated availability and deployment, Janssen, together with its Affiliates, is at risk expanding its internal and external global manufacturing network for the Vaccine Candidate, i.e. prior to the generation of the clinical data that is usually available before contemplating such further investment in a candidate, and in parallel to the development of the commercial scale, manufacturing process.

E. On 27 February 2021, the U.S. Food and Drug Administration issued an emergency use authorization for the Vaccine Candidate for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and on 12 March 2021 the Vaccine Candidate was listed for emergency use by the World Health Authority ("**WHO EUL**"). Janssen is in discussion with other regulatory authorities around the world, on the timing for and manner in which Janssen could receive appropriate marketing approvals for the Vaccine Candidate.

F. By virtue of (i) a letter dated 23 February 2021 issued to Janssen by Dr ZL Mkize, MP (Minister of Health of the Republic of South Africa) and TT Mboweni, MP (Minister of Finance of the Republic of South Africa), attached hereto as Exhibit E (the "**Comfort Letter**") and (ii) the obligations under this Agreement, the Government Purchaser has committed to putting in place on or before 30 April 2021 and operating thereafter a No Fault Compensation System (as defined below) that complies with the minimum requirements set forth in Exhibit B of this Agreement.

G. The Government Purchaser and Janssen entered into an advance purchase agreement with an effective date of 26 February 2021 (the "**APA**"), setting forth the terms and conditions

based upon which the Government Purchaser would purchase, and Janssen would supply, the Vaccine Volume (as defined in the APA) of eleven million (11,000,000) Vaccine Doses (as defined in the APA). Pursuant to clause 2.3 of the APA, Government Purchaser may, on giving written notice to Janssen, request to procure the advance purchase of an additional volume of up to twenty million (20,000,000) Vaccine Doses (as defined in the APA) in excess of the Vaccine Volume (as defined in the APA). Government Purchaser provided such notice to Janssen on 4 March 2021. For the purposes of the APA, this Agreement constitutes the "Additional Doses Agreement" (as defined in the APA).

H. The Government Purchaser now wishes to enter into this Agreement to secure, in advance, the availability of the Additional Vaccine Volume (as defined below) in accordance with the terms and conditions as set out in this Agreement and pursuant to clause 2.3 of the APA. This Agreement shall apply to the Additional Vaccine Volume only. It shall not apply to the purchase of the Vaccine Volume or Further Vaccine Volume (each as defined in the APA) or for use other than for the Purpose (as defined below), irrespective of the number of individuals who will ultimately be protected with the Additional Vaccine Volume.

IT IS AGREED AS FOLLOWS:

1. DEFINITIONS AND INTERPRETATION

1.1 Definitions

"**Additional Vaccine Volume**" means a volume of 20,000,000 (twenty million) Vaccine Doses;

"**Adjudicated**" shall mean a final determination by a court of competent jurisdiction, in respect of which the time for filing an appeal has expired or all appeals have been exhausted;

"**Adjusted Price**" has the meaning given to it in clause 3.2;

"**Affiliate**" means, with respect to Janssen, any person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with Janssen. For the purposes of this definition, "**control**" and, with correlative meanings, the terms "**controlled by**" and "**under common control with**" means:

(a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or

(b) the ownership, directly or indirectly, of at least fifty per cent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity);

"**Agreement**" means this Advance Purchase Agreement (including its Exhibits), as amended, supplemented, replaced or novated from time to time in accordance with its terms and conditions;

"**APA**" has the meaning given to it in Recital G;

"**Approval Long Stop Date**" has the meaning given to it in clause 18.4(c);

"**Arbitration Rules**" has the meaning given to it in clause 23.2.1;

"**Availability**" means, with respect to any quantity of the Additional Vaccine Volume, its presence at a Janssen central warehouse, quality released by Janssen, and prior to shipment and Delivery to the Government Purchaser; and the terms "**Available**" and "**made Available**" (or any similar construct) shall be construed accordingly;

"**Business Day**" means any day other than a Saturday, Sunday or official public holiday in the Republic of South Africa;

"**Claim**" has the meaning given to it in clause 17.3:

"**Confidential Information**" means any and all information, data, documents and materials (in any form and including all copies), regardless of the form or means of communication and whether such information is labelled or otherwise identified as confidential, including customer, product, business, commercial, financial, technical, purchasing, specifications, know-how and other information (including analyses, compilations, studies, reports, interpretations, projections, forecasts and records), disclosed by one Party (or its Affiliates) to the other Party (or its Affiliates) before, on or after the Effective Date. For the purpose of this Agreement, Janssen's Confidential Information shall be deemed to include this Agreement as well as any information provided by or on behalf of Janssen or its Affiliates to the Government Purchaser (or any ministry or other agency thereof) under or in connection with this Agreement and all information that is disclosed in connection with the Vaccine Candidate or the COVID Vaccine;

"**Cold Chain**" means, in relation to Additional Vaccine Volume, temperature-controlled storage and transport conditions in accordance with the Specifications as established in the Regulatory Approval;

"**Comfort Letter**" has the meaning given to it in Recital F;

"**COVID Vaccine**" means the final drug product form of the Vaccine Candidate, the substance of which has received Regulatory Approval;

"Delivery" means, in respect of any quantity of Additional Vaccine Volume, delivery of that quantity of Additional Vaccine Volume by Janssen to the Government Purchaser at the Delivery Address in accordance with the requirements of clause 8 and the terms "**Deliver**" and "**Delivered**" (or any similar construct) shall be construed accordingly;

"**Delivery Address**" means OR Tambo International Airport, 1 Jones Rd, Kempton Park, Johannesburg, South Africa, 1632;

"**Dispute**" has the meaning given to it in clause 23.2.1;

"**Down Payment**" has the meaning given to it in clause 10.1;

"**Effective Date**" means the date mentioned at the beginning of this Agreement;

"**Expected Approval Date**" has the meaning given to it in clause 8.2.3;

"**Failure to comply with cGMP**" shall mean a failure of compliance with the cGMP rules directly causing death or serious physical injury or illness of a Vaccinated Individual;

"**Final Availability Schedule**" has the meaning given to it in clause 8.2.2;

"**Global Not-for-Profit Framework**" has the meaning given to it in clause 3.2;

"**GMO**" has the meaning ascribed to such term in the GMO Act;

"**GMO Act**" means the Genetically Modified Organisms Act, 15 of 1997

"**cGMP**" or "**current Good Manufacturing Practices**" means the current good manufacturing practices required by the standards, rules, principles and guidelines promulgated by (i) EU Directive 2001/83/EC (as amended by Directive 2004/27/EC), EU Directive 2003/94/EC and EudraLex - Volume 4 of the Rules Governing Medicinal Products in the EU entitled "EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use", (ii) the Food and Drug Administration under the United States Federal Food, Drug and Cosmetic Act, 21 C.F.R. § 210 et seq. or under the Public Health Service Act, Biological Products, 21 C.F.R. §§600-610) and (iii) WHO TRS 999 and TRS 961, relating to manufacturing practices for pharmaceutical products (including ingredients, testing, storage, handling, ingredients, seed lots, cell banks and intermediates, bulk and finished products), in each case as applicable to and at the time of manufacture of the COVID Vaccine;

"**Good Distribution Practices**" or "**GDP**" means current good distribution practices for medicinal products, as set forth in (i) the EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01), and (ii) WHO TRS 957, Annex 5, WHO Good Distribution Practices for Pharmaceutical Products, in each case as applicable to and at the time of distribution of the COVID Vaccine;

"**Indemnified Persons**" has the meaning given to it in clause 17.1;

"**Intellectual Property Rights**" means patents, utility models, rights to inventions, copyright and neighbouring and related rights, moral rights, trademarks and service marks, business names and domain names, rights in get-up and trade dress, goodwill and the right to sue for passing off or unfair competition, rights in designs, rights in computer software, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets) and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world;

"**Janssen Material Breach**" means a failure by Janssen to make Available any quantity of Additional Vaccine Volume by the date which falls one (1) year after the date set out for Availability of such quantity of the Additional Vaccine Volume in the Final Availability Schedule, despite all conditions set out in clause 4.2 being satisfied;

"**Losses**" has the meaning given to it in clause 17.1;

"**Law**" means all civil codes, statutes, legislation, regulations, rules, by-laws, instruments, rules of common law, judgments, decrees or orders of any governmental, administrative, supervisory, regulatory or determinative authority, agency, court or other organisation of any jurisdiction, in each case which is established by, or having the authority of, law, and other measures or decisions having the force of law in any jurisdiction from time to time;

"**Material Breach**" means, (i) in the case of Janssen, a Janssen Material Breach or, (ii) in the case of the Government Purchaser, any material breach by the Government Purchaser of this Agreement (including any breach by the Government Purchaser of its payment obligations under clause 10);

"**No Fault Compensation System**" means the no fault compensation system provided for under the Disaster Management Act, 57 of 2002, that provides, amongst other matters, a system of compensation to individuals who have been vaccinated with the COVID Vaccine or Vaccine Candidate and who suffer serious physical injury or death caused by the COVID Vaccine or Vaccine Candidate, without the need to demonstrate a defect in the COVID Vaccine or Vaccine Candidate or any fault by a person. The No Fault Compensation System is in the process of being established (as confirmed by the Government Purchaser in the Comfort Letter and its obligations under this Agreement) and shall be maintained by the Government Purchaser in accordance with the minimum requirements set forth in Exhibit B;

"**Nonconforming COVID Vaccine**" has the meaning given to it in Exhibit C;

"**Price**" has the meaning given to it in clause 3.1;

"**Price Balance**" has the meaning given to it in clause 10.2;

"**Product Warranty**" means the warranty given by Janssen to the Government Purchaser under clause 8.7.1;

"**Programme**" means the Government Purchaser's national COVID-19 vaccine procurement and roll-out programme;

"**Purpose**" means use of the Additional Vaccine Volume, directly by the Government Purchaser or indirectly by a Third Party engaged by the Government Purchaser, in the Territory (and only in the Territory) to vaccinate individuals in the Territory against SARS-CoV-2/COVID-19, prior to its applicable Vaccine Expiry Date;

"**Regulatory Approval**" means regulatory approval (emergency use under section 21 of the Act or otherwise under section 15 of the Act) for the legal marketing, importation, distribution, sale, administration and use of the Vaccine Candidate in the Territory granted or issued by the Regulatory Authority pursuant to the Medicines and Related Substances Act No. 101 of 1965 Act and regulations applicable thereunder (the "**Act**");

"**Regulatory Authority**" means the South African Health Products Regulatory Authority, or any successor agency thereto;

"**Residence**" means the place of permanent home or principal establishment;

"**Specifications**" means the specifications and requirements for the COVID Vaccine as set out in the Regulatory Approval (as may be amended following the relevant regulatory processes and approvals by the Regulatory Authority under applicable Law from time to time);

"**Tentative Availability Schedule**" means the tentative availability schedule for the Additional Vaccine Volume as set out in Exhibit A;

"**Territory**" means the Republic of South Africa, including all of its provinces and territories;

"**Third Party**" means any person other than the Government Purchaser, Janssen, or Janssen's Affiliates;

"**USD**" means United States Dollars, the legal currency of the United States of America;

"**Vaccinated Individual**" means any individual who has been administered the COVID Vaccine (or, as the case may be, any individual, group, entity or organization purporting to represent, act on behalf of, recover for or in respect of, or seek damages with respect to, any such individual or group of such individuals);

"**Vaccine Expiry Date**" means, with respect to any vial of the COVID Vaccine, the date on which the shelf life of such vial of COVID Vaccine ends;

"**Vaccine Candidate**" means Janssen's investigational SARS-CoV-2 vaccine, Ad26.COV2-S, recombinant;

"**Vaccine Dose**" means, with respect to the COVID Vaccine, one single injection of up to $1x10^{11}$ viral particles (one dose);

"**Willful Default**" means a deliberate act or omission by a Party which results in a breach of this Agreement and where (i) at the time of that act or omission that Party knew that material loss or harm would arise directly from its acts or omissions; (ii) such act or omission was taken with the primary intent of causing such loss or harm and achieving a wrongful purpose, and (iii) such act or omission was taken without legal or factual justification (it being agreed and acknowledged by the Parties, however, that any action consistent with rules or guidance set out by the WHO, Government Purchaser or any other government (be it state, provincial, municipal, local or regional) in the Territory, or any public agency, body or other public or regulatory authority in the Territory (including the Regulatory Authority), and any action, test or results disclosed to a regulatory authority as a part of receiving regulatory approval for the Vaccine Candidate in the Territory shall not be considered to be Willful Default); and

"**Wilful Misconduct**" shall mean an act or omission that is taken (i) with intentional disregard of a known risk in the manufacture of the COVID Vaccine that is so great as to make it highly probable that the harm will outweigh the benefit, (ii) without legal or factual justification, and (iii) with the intent of achieving a wrongful purpose (it being understood, however, that any action consistent with rules or guidance set out by the Government Purchaser, any governmental authority or any other government (be it state, provincial, municipal, local or regional) in the Territory, or any public agency, body or other public or regulatory authority in the Territory, and any action, test or results disclosed to a regulatory authority as a part of

receiving regulatory approval for the COVID Vaccine in the Territory, shall not be considered to be Wilful Misconduct).

1.2 **Interpretation**

1.2.1 Unless the context otherwise requires, the following rules of interpretation shall apply to this Agreement:

(a) words in the singular include the plural and in the plural include the singular;

(b) use of any gender or neuter includes the other genders and neuter;

(c) references to a particular statute or statutory provision or other Law shall:

(i) include all subordinate legislation made from time to time under that statute, statutory provision or other Law; and

(ii) be construed as a reference to such Law as amended, re-enacted, consolidated, supplemented, replaced or renumbered (or as its application or interpretation is changed or affected by other Laws) from time to time and as was, is, or will be (as the case may be) applicable at the time in question except that as between the Parties, no such amendment or modification shall apply for the purposes of this Agreement to the extent that it would impose any new or extended liability, obligation or restriction on, or otherwise adversely affect the rights of, any Party;

(d) references to "**clauses**" and "**Exhibits**" are to clauses of, and exhibits to, this Agreement;

(e) references to a "**day**" shall mean a period of twenty four (24) hours running from midnight to midnight and reference to any time or date shall, save where otherwise expressly stated to the contrary, be a reference to the time or date (as the case may be) in Brussels, Belgium and references to a "**month**" or "**year**" shall respectively mean a calendar month and calendar year;

(f) references to a "**person**" shall be construed so as to include:

(i) any individual, firm, body corporate, regulatory authority (including the Regulatory Authority), other governmental authorities, joint venture, association, undertaking, partnership or limited partnership (whether or not having separate legal personality); and

(ii) a reference to the estate, successors, permitted transferees and permitted assignees of any of such person;

(g) any reference to a **Party** or the **Parties** is to a party or the parties (as the case may be) to this Agreement and shall include legal successors and/or any permitted assignees of a Party;

(h) the words "**include**", "**including**" or "**in particular**" shall not limit the generality of any preceding words or be construed as being limited to the same class as any preceding words where a wider construction is possible;

(i) the words "**intends to**" shall be construed as a right to do something (and shall not impose an obligation on a Party); and

(j) references to "**written**" or "**writing**" shall include all data in written form in the English language, whether represented in hand-written, facsimile, printed, electronic or other format (including e-mail, but excluding short-message-service (SMS) or other temporary electronic messages).

2. PURCHASE COMMITMENTS

2.1 Firm Commitment

In consideration of Janssen's obligations under this Agreement, the Government Purchaser shall advance purchase and pay for the Additional Vaccine Volume in accordance with clause 10.

3. PRICE

3.1 The price per single Vaccine Dose of the Vaccine Volume purchased hereunder shall be ten United States Dollars (USD 10) ("**Price**"). The Government Purchaser acknowledges that Janssen is willing to sell the Vaccine Volume at the Price in reliance on the Government Purchaser's agreement that the Additional Vaccine Volume shall be used solely for the Purpose.

3.2 The Parties acknowledge that Janssen is developing a framework for determining the global price for its Vaccine Dose, to strengthen its commitment to making its initial production allocation of the Vaccine Candidate in 2021 available on a not-for-profit basis. This framework will be subject to a review process by a third party audit firm (such framework, the "**Global Not-for-Profit Framework**"). Janssen shall review the Price in light of the Global Not-for-Profit Framework, and to the extent Janssen decides, in Janssen's sole discretion acting in good faith, that the Price is higher than the global price for the Vaccine Dose calculated in accordance with its Global Not-for-Profit Framework, Janssen shall notify the Government Purchaser in writing thereof and the Price shall then be adjusted downwards in accordance with the Global Not-for-Profit Framework (the "**Adjusted Price**"). To the extent the Government Purchaser has already paid the Price for (any quantity of) the Additional Vaccine Volume, Janssen shall (directly or indirectly through one of its Affiliates) refund the difference between the Price and the Adjusted Price to the Government Purchaser for such Additional Vaccine Volume as soon as reasonably practicable. If the Price is adjusted in accordance with this clause 3.2, references in this Agreement to the "Price" shall be deemed to be references to the "Adjusted Price".

3.3 The Parties agree that the Global Not-for-Profit Framework shall remain confidential and that Janssen is under no obligation to disclose to the Government Purchaser the Global Not-for-Profit Framework, and nothing in this Agreement shall permit the Government Purchaser to assess, audit, analyse, question, or otherwise have access to or evaluate, the Global Not-for-Profit Framework.

3.4 The Price shall be exclusive of any and all costs, duties, fees or other compensation in relation to the allocation, maintenance, distribution, storage, transport, administration and management of the Additional Vaccine Volume following Delivery, and, for clarity, of VAT and other taxes (as further set out in clause 10.8). The Government Purchaser shall be

solely responsible for any and all costs in relation to the allocation, maintenance, distribution, storage, transport, administration, and management of the Additional Vaccine Volume following Delivery and for payment of VAT and other taxes.

3.5 The Government Purchaser acknowledges that the price payable for COVID Vaccine that is for use other than for the Purpose, may be higher than the Price, and that the Global Not-For-Profit Framework is expected to apply only to Janssen's initial production of the Vaccine Candidate in 2021 (which for the avoidance of doubt will include the Additional Vaccine Volume whenever delivered), after which Janssen expects to transition to a commercial pricing framework for the COVID Vaccine.

4. DELIVERY CONDITIONS

4.1 The Government Purchaser represents and warrants to Janssen that:

(a) it shall, on or before 30 April 2021 by way of publishing the relevant Act of Parliament (previously signed by the President of the Republic of South Africa) in the South African Government Gazette, establish a No Fault Compensation System that provides, amongst other matters, a system of compensation to individuals who have been vaccinated with the COVID Vaccine or Vaccine Candidate and who suffer physical injury or death caused by the COVID Vaccine or Vaccine Candidate, without the need to demonstrate a defect in the COVID Vaccine or Vaccine Candidate or any fault by a person, in accordance with the minimum requirements set forth in Exhibit B of this Agreement and otherwise in form and substance satisfactory to Janssen; and

(b) such No Fault Compensation System will be in full force and effect upon its publication in the South African Government Gazette.

4.2 Janssen's Availability and Delivery obligations in respect of (any quantity of) the Additional Vaccine Volume under this Agreement, shall be subject to and conditional upon the satisfaction of the following cumulative conditions:

(a) the Regulatory Authority having granted or issued the Regulatory Approval and such Regulatory Approval not having been subsequently withdrawn, suspended or discontinued;

(b) Janssen having scaled up and expanded its manufacturing capacity of the COVID Vaccine, so that it is able to produce and make Available the Additional Vaccine Volume, it being understood that (i) Janssen relies also on third party CMOs to achieve such effect, (ii) Janssen shall use commercially reasonable efforts to scale up and expand its manufacturing processes, and (iii) as at the Effective Date, Janssen has not yet scaled up and expanded its manufacturing processes at anticipated mass scale;

(c) Janssen being able to lawfully export (finished or unfinished portions of) the Additional Vaccine Volume from the applicable country or countries of production to the Territory and without prejudice to clause 6.4, to import the Additional Vaccine Volume into the Territory;

(d) to the extent that the COVID Vaccine is regulated as a GMO under the GMO Act, the necessary permit has been issued by the Registrar at the Department of

Agriculture, Forestry and Fisheries to authorise importation, exportation, transit, development, production, release, distribution, use, storage and application of the COVID Vaccine; or the COVID Vaccine has been exempted from such authorisation and permit;

(e) the No Fault Compensation System (i) having been enacted in accordance with clause 4.1 including the minimum requirements set forth in Exhibit B, (ii) remaining in full force and effect, and (iii) being enforced and continuing to provide compensation to individuals who have been vaccinated with the COVID Vaccine or Vaccine Candidate and who suffer serious physical injury or death caused by the COVID Vaccine or Vaccine Candidate, without the need to demonstrate a defect in the COVID Vaccine or Vaccine Candidate or any fault by a person;

(f) the Government Purchaser having paid the Down Payment in accordance with clause 10.1 and having paid the applicable Price Balance in accordance with clause 10.5; and

(g) the Government Purchaser having complied with all of its other obligations under this Agreement to be satisfied prior to Delivery of (any quantity of) the Additional Vaccine Volume.

5. ADDITIONAL VACCINE VOLUME

5.1 Subject to the terms and conditions of this Agreement, Janssen shall Deliver the Additional Vaccine Volume to the Government Purchaser.

5.2 The Government Purchaser acknowledges and agrees that:

(a) Janssen's expectation, as at the Effective Date, based on the current status of development of the Vaccine Candidate, is that to address the current pandemic, and depending on the results generated as part of the overall clinical development plan, each Vaccine Dose will consist of one (1) single injection of up to $1x10^{11}$ viral particles (one (1) dose);

(b) the final total dosage and administration schedule of COVID Vaccine required to protect one (1) individual against SARS-CoV-2/COVID-19 has not been determined as of the Effective Date and, without prejudice to clause 5.2(c), shall be determined solely by Janssen based on data generated in ongoing clinical trials; Janssen shall be entitled to unilaterally adjust the definition of Vaccine Dose set out in this Agreement after the Effective Date based on data generated as part of its ongoing clinical trials;

(c) Janssen provides no warranty that a Vaccine Dose will be sufficient to protect one (1) individual against COVID-19, or that the COVID Vaccine is safe or efficacious; and

(d) this Agreement relates only to the Delivery of the Additional Vaccine Volume to the Government Purchaser and does not regard or provide any assurances on the number of individuals who can or will ultimately be protected with the Additional Vaccine Volume.

5.3 Once Janssen has determined the final total dosage and administration schedule of the Vaccine Candidate, Janssen shall, as soon as reasonably practicable, inform the Government Purchaser of such final total dosage and administration schedule.

6. COOPERATION

6.1 The Government Purchaser shall assist Janssen, on Janssen's reasonable request, and shall work with the Regulatory Authority and such other governmental authorities (including, as applicable, provincial and/or municipal authorities) to facilitate and expedite the review of all licenses, permits, authorizations, legislative or regulatory exemptions and activities, testing and subsequent releases in relation to the Vaccine Candidate and/or the COVID Vaccine in the Territory, including the Regulatory Approval.

6.2 The Government Purchaser shall, upon enactment of the No Fault Compensation System:

(a) maintain the No Fault Compensation System in full force and effect and in accordance with the minimum requirements set forth in Exhibit B to cover the Additional Vaccine Volume purchased under this Agreement;

(b) adequately fund (or procure that it is adequately funded) the No Fault Compensation System; and

(c) require individuals entitled to compensation thereunder to seek redress from the No Fault Compensation System.

6.3 For the avoidance of doubt, the Government Purchaser understands and expressly agrees that if at any time after the Effective Date the No Fault Compensation System is cancelled, in any way diminished, limited or reduced in scope such that it no longer satisfies the minimum requirements set forth in Exhibit B, Janssen shall immediately and automatically be released from its obligations to make Available and Deliver any quantity of the Additional Vaccine Volume under this Agreement.

6.4 The Government Purchaser acknowledges that (i) Janssen's supply chain for the COVID Vaccine is global, (ii) Janssen will supply the Vaccine Doses from a variety of manufacturing sites and countries, and (iii) in order for Janssen to manufacture the COVID Vaccine at global scale and fulfil its obligations to all purchasers of the Vaccine Candidate and the COVID Vaccine (including the Government Purchaser), it is necessary that the Vaccine Candidate and the COVID Vaccine, and any finished or unfinished portions thereof, including any related raw materials and components, are able to move freely across national borders. The Government Purchaser shall permit Janssen and its Affiliates, or procure that Janssen and its Affiliates are permitted, to import into, export from, or otherwise move freely through, the Territory the Vaccine Candidate and the COVID Vaccine, and any finished or unfinished portions thereof, including any related raw materials and components. For clarity, the Government Purchaser, shall not impose any embargoes, export or import restrictions, quota or other restrictions or prohibitions on the Vaccine Candidate or the COVID Vaccine, and any finished or unfinished portions thereof, including any related raw materials and components, or fail to grant necessary licenses or consents for any such free movement.

7. ORDERS OF ADDITIONAL VACCINE VOLUME

This Agreement constitutes a binding order by the Government Purchaser, and acceptance of such order by Janssen, for the purchase of the Additional Vaccine Volume, such Additional Vaccine Volume to be made Available and Delivered by Janssen in accordance with clause 8. If and to the extent required by Janssen, the Government Purchaser shall issue a purchase order (in the format as agreed by Janssen and the Government Purchaser) to implement its binding order under this Agreement, it being understood that any such purchase order shall under no circumstances impact the Government Purchaser's obligations under this Agreement.

8. DELIVERY OF ADDITIONAL VACCINE VOLUME

8.1 Conditionality of Janssen's Delivery Obligation.

8.1.1 Janssen agrees to make Available, for subsequent Delivery, the Additional Vaccine Volume in accordance with the terms of this Agreement, subject to satisfaction of the conditions in clause 4.

8.2 Availability Schedule.

8.2.1 As at the Effective Date, Janssen tentatively expects that the Additional Vaccine Volume shall be made Available for subsequent Delivery to the Government Purchaser on the schedule and in the quantities as set out in the Tentative Availability Schedule. The Government Purchaser acknowledges and agrees that:

(a) the Tentative Availability Schedule is a best case scenario and assumes the Additional Vaccine Volume will be either created by improvements in Janssen's supply capacity or be sourced with the cooperation of other customers for the COVID Vaccine, and as such no assurances can be given by Janssen that such improvements will happen or that other customers will give up their doses; and

(b) the quantities set forth in the Tentative Available Schedule may not be available at the time set forth in such schedule, and Janssen can therefore not be held responsible if such quantities of Vaccine Doses are ultimately not delivered in accordance with the Tentative Availability Schedule.

8.2.2 After the Effective Date, Janssen intends to refine and, to the extent possible, update the Tentative Availability Schedule with the intention to provide the Government Purchaser with a final availability schedule as soon as reasonably practicable after the Effective Date (the "**Final Availability Schedule**").

8.2.3 The schedule and quantities set out in the Tentative Availability Schedule are based on Janssen's current assumption that Regulatory Approval will be granted or issued on or prior to 1 May 2021 (the "**Expected Approval Date**"), and the Government Purchaser acknowledges that if Regulatory Approval is not granted or issued by the Expected Approval Date, Janssen shall be entitled to adjust such schedule and quantities as Availability (and subsequent Delivery) will likely be delayed.

8.2.4 The schedule set out in the Tentative Availability Schedule reflects, and the schedule that will be set out in the Final Availability Schedule will reflect, the quarter in which the applicable quantity of Additional Vaccine Volume shall be made Available (based on Janssen's standard requirements as to specifications, packaging, labelling, release testing

and other matters (other than any such activities that are normally conducted within the Territory by Janssen or its Affiliates)). The Government Purchaser acknowledges that:

(a) such schedule does not necessarily reflect the schedule on which the Additional Vaccine Volume will be Delivered to it;

(b) the exact dates of Delivery of the Additional Vaccine Volume will depend on various factors and requirements to be satisfied after the Additional Vaccine Volume has been quality released by Janssen, including requirements under local laws and regulations (such as local requirements for testing, evaluation and release by the South African Health Products Regulatory Authority, local testing and local release by competent authorities within the Territory, export and import restrictions, etc.) and shipping time from Janssen's distribution centres to the Delivery Address; and

(c) accordingly, Janssen cannot provide any assurance or commitment to the Government Purchaser as to the schedule and timing of Delivery of Additional Vaccine Volume.

8.2.5 The grant or issuance of the Regulatory Approval earlier than the Expected Approval Date shall not require Janssen to make Available or Deliver any quantities of the Additional Vaccine Volume ahead of the Tentative Availability Schedule or the Final Availability Schedule.

8.2.6 Janssen shall bear no liability if Availability cannot take place in accordance with the Tentative Availability Schedule or the Final Availability Schedule and/or if Delivery cannot take place within the time periods expected by the Government Purchaser, unless the failure is due to Janssen's Willful Default, provided however that Janssen shall use reasonable commercial efforts to make the applicable quantity of Additional Vaccine Volume Available and/or to proceed with Delivery thereof at the earliest possible date thereafter.

8.2.7 Janssen shall inform the Government Purchaser, as part of the operational discussion platform referred to in clause 14, of any expected material change in the Availability of the Additional Vaccine Volume as per the Tentative Availability Schedule or Final Availability Schedule. In such case, Janssen shall provide to the Government Purchaser an updated schedule with the intention to make Available the Additional Vaccine Volume within a schedule that is as close as reasonably possible to the Tentative Availability Schedule taking into account Janssen's constraints as set forth in clause 8.2.1(a).

8.3 **Delivery.**

8.3.1 The Additional Vaccine Volume shall be Delivered by Janssen to the Government Purchaser, and the Government Purchaser shall accept Delivery of the Additional Vaccine Volume, CIP (Incoterms 2020), at the Delivery Address. The Government Purchaser acknowledges that Janssen will make multiple Deliveries over a period of time, in varying quantities, depending on Availability.

8.3.2 Risk of loss and title in the Additional Vaccine Volume shall transfer to the Government Purchaser upon Delivery in accordance with clause 8.3.1

8.4 **Form of Delivery.**

8.4.1 Additional Vaccine Volume will be Delivered in collector boxes, each box containing a certain quantity of primary packaged and labelled multi-dose vials without preservative(s),

and each vial containing a certain quantity of Vaccine Doses. Janssen shall inform the Government Purchaser in due course of any specificities of shipment packaging and of ordering of the Additional Vaccine Volume.

8.4.2 The Government Purchaser acknowledges that:

(a) Janssen's current expectation is that, to address the current pandemic, regulatory authorities will require all Vaccine Doses comprised in a vial to be used within four (4) to six (6) hours after administration of the first dose of the vial (provided the Vaccine Doses are kept refrigerated in accordance with Specifications); and

(b) given the current pandemic and the urgency of required Delivery of the Additional Vaccine Volume:

(i) Janssen may not be able to Deliver the Additional Vaccine Volume to the Government Purchaser fully in accordance with the usual packaging and labelling requirements for medicinal products approved for commercialization within the Territory. The Government Purchaser shall accept Delivery of any Additional Vaccine Volume in a generic packaged and labelled form suitable for usage in the Territory; and

(ii) no paper leaflets will be Delivered, and the Government Purchaser acknowledges and accepts that any information with respect to the COVID Vaccine will be provided via electronic leaflets, at Janssen's discretion.

8.5 **Import**

The Government Purchaser is responsible for compliance with all applicable import requirements for its purchases under this Agreement.

8.6 **Non-conforming Additional Vaccine Volume**

If the Government Purchaser alleges that any quantity of the Additional Vaccine Volume Delivered to it under this Agreement is Nonconforming COVID Vaccine, the provisions of Exhibit C shall apply, it being understood that under no circumstances shall the provisions of Exhibit C impact Janssen's indemnification rights under clause 17 (*Indemnification*). In this instance, the Government Purchaser shall be entitled to a refund or replacement of the Nonconforming COVID Vaccine in accordance with and subject to the terms of Exhibit C.

8.7 **Product Warranty**

8.7.1 Janssen warrants that as at the time of Delivery pursuant to clause 8.3, Janssen has manufactured, filled, stored, packaged, labelled, released and Delivered the Additional Vaccine Volume in compliance with cGMP applicable at the time of Delivery, to the extent that each standard of cGMP is or can be applicable, and taking into account any waiver, forbearance or exemption granted or allowed by the Government Purchaser or any other applicable regulatory authority in the Territory.

8.7.2 In the event that Janssen is in breach of the Product Warranty with respect to (any quantity of) the Additional Vaccine Volume, then, to the extent such Additional Vaccine Volume has not been administered to individuals at the time such breach is identified, Janssen shall (directly or indirectly through one of its Affiliates), as soon as reasonably practicable, refund the Price for such Additional Vaccine Volume to the extent already paid by the Government

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Purchaser (it being understood, for the avoidance of doubt, that such refund shall then apply only with respect to such Additional Vaccine Volume in respect of which a breach of the Product Warranty has been identified, which has not been administered to individuals, and which the Government Purchaser confirms will not be so administered). Such refund shall be the only remedy available to the Government Purchaser in respect of this clause 8.7.

9. USE OF ADDITIONAL VACCINE VOLUME

9.1 Following Delivery in accordance with clause 8.3, the Government Purchaser shall be solely responsible and liable for the subsequent inspection, allocation, maintenance, distribution, storage, transport, administration, and management of the Additional Vaccine Volume, along with any related follow-on care, for the Purpose and in accordance with this Agreement and applicable Laws.

9.2 The Government Purchaser acknowledges and agrees that, for any quantity of the Additional Vaccine Volume it receives from Janssen under this Agreement, it shall establish and maintain a Cold Chain distribution channel in compliance with:

(a) Good Distribution Practices;

(b) Specifications; and

(c) Janssen's reasonable instructions for storage and distribution thereof (including instructions with respect to thawing).

9.3 Janssen may audit the Government Purchaser's distribution channels that are used for Additional Vaccine Volume to determine whether such channels are in compliance with Cold Chain requirements, Good Distribution Practices, Specifications, and Janssen's reasonable instructions for storage and transportation of the Additional Vaccine Volume. If Janssen discovers any non-compliance during such audit, Janssen will inform the Government Purchaser thereof, and the Government Purchaser shall then cure such non-compliance within the cure period, being not less than 10 (ten) Business Days, communicated by Janssen (acting reasonably). If by the end of such cure period such non-compliance is not cured, Janssen may (after prior consultation with the Government Purchaser) take measures and actions it considers reasonably appropriate.

9.4 The Government Purchaser further acknowledges and agrees that an incoming inspection of Additional Vaccine Volume shall be performed by it. At the Government Purchaser's reasonable request, Janssen will use commercially reasonable efforts to provide such technical assistance as the Government Purchaser may reasonably require to enable the Government Purchaser to perform such incoming inspection.

9.5 The Government Purchaser acknowledges and agrees that Janssen is selling the Additional Vaccine Volume to the Government Purchaser at the Price solely for use for the Purpose (and the Government Purchaser agrees that it shall not use, nor permit the use of, the Additional Vaccine Volume for any purpose other than the Purpose).

9.6 The Government Purchaser shall:

(a) not apply any mark-up or other price differentials to any resale price in the distribution of the Additional Vaccine Volume. For clarity, nothing in this clause 9.6(a) shall prevent the Government Purchaser from: (i) seeking reimbursement

from its customers of any additional transport and/or distribution costs it would have incurred in the distribution of the Additional Vaccine Volume in the Territory, and (ii) applying any discounts in the distribution of the Additional Vaccine Volume in the Territory (provided that such discounts are applied uniformly throughout the Territory);

(b) except for the Purpose, not re-sell, donate or otherwise distribute any Additional Vaccine Volume to any Third Party (including with a view to vaccinate individuals outside of the Territory) without the prior written approval of Janssen, which consent shall not be unreasonably withheld or delayed (and when considering whether to give such approval, Janssen shall take into account, among other factors, the possibility for the Vaccine Doses to be used in markets other than South Africa where such doses may have a higher efficacy);

(c) not use any quantity of the Additional Vaccine Volume after the Vaccine Expiry Date;

(d) in case the Government Purchaser has any unadministered stock of the Additional Vaccine Volume past the Vaccine Expiry Date, the Government Purchaser shall promptly notify Janssen thereof and destroy such Additional Vaccine Volume at its own cost and provide Janssen with a certificate of destruction; and

(e) not use any quantity of the Additional Vaccine Volume which has not been maintained in conformance with the Cold Chain requirements and, in case of occurrence of temperature excursions, follow the procedures set out in item 5 (*Cold Chain & Temperature Excursions*) of Exhibit D (*Quality Requirements*).

10. FINANCIAL PROVISIONS

10.1 Down Payment.

The Government Purchaser shall make a down payment of USD 50,000,000 (fifty million) to Janssen ("**Down Payment**") within fifteen (15) Business Days after the Effective Date, by wire transfer of immediately available funds on the following bank account of Janssen:

Name of bank: ING

Exact denomination of account holder: Janssen Pharmaceutica NV

Full account number including bank codes IBAN: [redacted]

[redacted]

Redacted by HJI 4 Sept 2023

10.2 Credit.

Janssen shall credit the Down Payment toward the price for the Additional Vaccine Volume Delivered by Janssen to the Government Purchaser at a rate of USD 2.50 per Vaccine Dose (such amount, the "**Credit**") and the Government Purchaser shall be liable, for each Vaccine Dose, to pay the difference between the Price and the Credit (the "**Price Balance**") in accordance with clause 10.4.

10.3 Refundability.

Subject to clause 22.10 (*Willful Default*) and except as set out in clause 18.5, the Down Payment shall not be refundable by Janssen to the Government Purchaser in any circumstances, including, if the Vaccine Candidate does not receive Regulatory Approval, if development and/or manufacturing of the Vaccine Candidate is unsuccessful, or any other condition set out in clause 4.2 is not satisfied.

10.4 **Price Balance.**

Prior to Delivery of any quantity of the Additional Vaccine Volume and as soon as any such quantity of the Additional Vaccine Volume is Available, Janssen shall invoice the Government Purchaser in accordance with clause 10.7 and the Government Purchaser shall pay to Janssen the Price Balance for such quantity of the Additional Vaccine Volume prior to Delivery thereof , in accordance with the payment terms set out in Janssen's invoice.

10.5 **Payment Default.**

If the Government Purchaser fails to pay (any portion of) the Down Payment(s) or Price Balance (as applicable) for any quantity of the Additional Vaccine Volume in accordance with this clause 10, Janssen may, refuse or delay any and all future Availability and Delivery of the Additional Vaccine Volume, or, pursuant to clause 18.3, terminate this Agreement.

10.6 **Currency.**

10.6.1 Any payments to be made by the Government Purchaser under this Agreement shall be made, and any invoices issued pursuant to this Agreement shall be issued, in United States Dollars ($ USD).

10.7 **Invoice.**

As and when each quantity of the Additional Vaccine Volume is made Available, Janssen shall issue a valid invoice for payment of the aggregate Price Balance in respect of such quantity pursuant to clause 10.4 to the Government Purchaser at the following address:

The Director-General of the National Department of Health
National Department of Health
Civitas Building,
222 Thabo Sehume Street
CBD
Pretoria
0001

10.8 **Taxes.**

10.8.1 All amounts payable by the Government Purchaser under this Agreement are exclusive of amounts in respect of value added tax chargeable from time to time (**"VAT"**), sales taxes and all other taxes, as well as customs and import fees and duties. The Government Purchaser is responsible to pay all such taxes, customs and import fees and duties in addition to any payments for the Additional Vaccine Volume under this Agreement as required by applicable Laws. To the extent Janssen has paid any customs and import fees and duties in relation to the import of the Additional Vaccine Volume, the Government Purchaser shall reimburse Janssen in respect of such costs. Where any taxable delivery for VAT purposes is made under this Agreement by Janssen, the Government Purchaser shall, on receipt of a

valid VAT invoice from Janssen, pay to Janssen or directly towards the relevant taxing authorities, in case required by applicable Laws, such additional amounts in respect of VAT as are chargeable on such delivery.

10.8.2 For the avoidance of doubt, where legally required, VAT may be charged on any quantity of the Additional Vaccine Volume under the conditions of applicable Laws. In such cases, the taxable amount for each Vaccine Dose shall be the Price (including the respective portion of the Down Payments).

10.9 **Late payments.**

10.9.1 Without prejudice to Janssen's other remedies under this Agreement, if the Government Purchaser fails to make a payment due to Janssen under this Agreement by the due date, then, the Government Purchaser shall pay interest on the overdue sum from the due date until payment of the overdue sum, whether before or after judgment. Interest under this clause 10.9.1 shall accrue each day at four percent (4%) a year above the Bank of England's base rate from time to time, but at four percent (4%) a year for any period when that base rate is below zero percent (0%), or any lower figure otherwise required by applicable Laws.

10.10 **Set off.**

All amounts due under this Agreement from the Government Purchaser to Janssen shall be paid in full without any set-off, counterclaim, deduction or withholding (other than any deduction or withholding of tax as required by applicable Laws). If any deductions or withholding of tax is required by applicable Laws to be made from any amounts due under this Agreement from the Government Purchaser to Janssen, the Government Purchaser shall pay to Janssen such additional sum as will, after the deduction or withholding has been made, leave Janssen with the same amount as it would have been entitled to receive in the absence of any such requirement to make a deduction or withholding.

11. REGULATORY APPROVAL

11.1 Janssen intends to submit; either in its own name or through one of its Affiliates or subcontractors, an application for Regulatory Approval as soon as reasonably practicable after successful development of the Vaccine Candidate, having regard to the estimated time required to secure the Regulatory Approval in order to make the Additional Vaccine Volume Available in accordance with the Tentative Availability Schedule. If, in the process of reviewing the results or progress of its clinical trials with respect to the Vaccine Candidate, Janssen reasonably determines that the ongoing or planned clinical trials are likely to be insufficient for Regulatory Approval, Janssen shall inform the Government Purchaser thereof and Janssen shall have no obligation to submit an application for Regulatory Approval of the Vaccine Candidate.

11.2 The Government Purchaser shall cooperate with Janssen and share any relevant information to facilitate the grant or issuance of the Regulatory Approval.

12. PHARMACOVIGILANCE AND QUALITY

12.1 The Government Purchaser shall inform Janssen of any Adverse Events Following Immunisation and Special Situations following use of the COVID Vaccine (together, if available, with the relevant lot/batch numbers of the relevant COVID Vaccine), within one

(1) day of date of first receipt. Such information shall be sent to Janssen in accordance with the method of exchange below:

General Mailbox: (secure e-mail only): AdverseEventZA@its.jnj.com

For the purposes of this clause 12.1:

"**Adverse Events Following Immunisation**" shall mean any untoward medical occurrence in a patient or a clinical-trial subject following immunisation, which does not necessarily have a causal relationship with usage of the COVID Vaccine. An Adverse Event Following Immunisation can therefore be any unfavourable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this medicinal product; and

"**Special Situations**" shall mean any special situation, including reports of exposure during pregnancy or breastfeeding, overdose, abuse and misuse, medication errors, suspected transmission of any infectious agents, outside of label use, occupational exposure, inadvertent or accidental exposure, failure of expected pharmacological action, unexpected therapeutic or clinical benefit, expired drug use and falsified medicine.

12.2 The allocation of roles and responsibilities between Janssen and the Government Purchaser set out in Exhibit D shall apply in relation to quality assurance matters in respect of the Additional Vaccine Volume.

13. REPRESENTATIONS AND WARRANTIES

13.1 Each Party represents and warrants to the other Party that:

(a) it has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; and

(b) this Agreement has been duly executed and delivered by it and constitutes a valid and legally binding obligation enforceable against it in accordance with the terms of this Agreement.

13.2 The Government Purchaser warrants to Janssen that:

(a) it has the right and/or requisite authorisation to perform under this Agreement and to order, purchase allocate, maintain, distribute, store, transport, administer, and manage the Additional Vaccine Volume in accordance with any applicable Law, including the provisions of national procurement Laws;

(b) it is executing the Agreement on behalf of the national government of the Republic of South Africa in its entirety; and

(c) by executing this Agreement on behalf of the national government of the Republic of South Africa in its entirety, such government is irrevocably and unconditionally bound by, and shall not challenge, the terms of this Agreement (including the provisions of clause 17 (*Indemnification*)) and this Agreement comprises a valid and legally binding obligation enforceable against such government in accordance with the terms of this Agreement.

13.3 Janssen warrants to the Government Purchaser that:

(a) as of the Effective Date, it is not under any contractual obligation to any Third Party in respect of the Additional Vaccine Volume or that conflicts with or is inconsistent in any material respect with the terms of this Agreement;

(b) it shall comply with all Laws that are applicable to its activities and operations under this Agreement; and

(c) all data and information that has been submitted to the Regulatory Authority in support of any applications for the necessary Regulatory Approval was, at the time of such submission and to the best of its knowledge, factually accurate and complete.

13.4 Except for the warranties set out in clauses 8.7, 13.1 and 13.3, Janssen disclaims, to the fullest extent permitted by Law, all warranties, express or implied (whether by Law, custom or course of dealing), including the implied warranties of merchantability and fitness for a particular purpose, and any warranty relating to the sufficiency of a single Vaccine Dose to protect one (1) individual against SARS-CoV-2/COVID-19 or the safety or effectiveness of the COVID Vaccine.

14. OPERATIONAL DISCUSSION PLATFORM

14.1 The Parties shall, after the Effective Date, set up an informal operational discussion platform to discuss, on an as-needed basis, certain operational matters regarding the implementation of this Agreement (such as, for instance, regulatory, supply chain, logistics and/or other relevant matters, including any requirements for issuance of (a) formal purchase order(s) to implement this Agreement).

15. INTELLECTUAL PROPERTY

15.1 Nothing in this Agreement shall grant either Party any rights to the other Party's Intellectual Property Rights. Under no circumstances does Janssen grant to the Government Purchaser or to any Third Party, by transfer, implication, estoppel or otherwise, any right, title, license or interest in any Intellectual Property Rights it or any of its Affiliates owns or controls in relation to, in connection with or resulting from the Vaccine Candidate, the COVID Vaccine or the Additional Vaccine Volume.

16. CONFIDENTIALITY

16.1 Each Party (a "**Receiving Party**") shall keep confidential and not disclose to any Third Party, nor use other than for the purpose of exercising its rights and performing its obligations under this Agreement, any Confidential Information of the other Party (a "**Disclosing Party**").

16.2 The obligations of confidentiality in clause 16.1 shall not apply to any use or disclosure expressly authorised by the Disclosing Party in writing or any information, data or materials which:

(a) is already lawfully possessed by the Receiving Party without any obligations of confidentiality or restrictions on use prior to receiving it from the Disclosing Party (whether before, on or after Effective Date), as documented by prior written records;

(b) is already in, or comes into, the public domain otherwise than through the Receiving Party's unauthorised disclosure;

(c) is obtained subsequently by the Receiving Party from a Third Party, which Third Party is not itself subject to any obligations of confidentiality;

(d) has been developed by the Receiving Party independently of any access to or use of any Confidential Information disclosed hereunder, as documented by the Receiving Party's written records; or

(e) is legally required to be disclosed in terms of Law.

16.3 The Receiving Party may only disclose Confidential Information to its employees, consultants, agents, officers, advisers and other representatives including in the case of Janssen, to its Affiliates and sub-contractors, on a need to know basis solely for the purpose of performing its obligations and exercising its rights under this Agreement, provided that the Receiving Party shall be responsible for actions and omissions of such employees, consultants, agents, officers, advisers, representatives, Affiliates or sub-contractors (as applicable), to whom Confidential Information is disclosed pursuant to this clause 16.3, and shall be liable as if such actions or omissions were those of the Receiving Party. Notwithstanding the forgoing, the Government Purchaser may only disclose Janssen's Confidential Information pursuant to this clause 16.3 to the government of any province or territory within the Territory, including any agency thereof, after providing advance written notice to Janssen of its intention to disclose such Confidential Information, and to the extent such government of any province or territory within the Territory, including any agency thereof agrees in writing to comply with the confidentiality provisions set out in this Agreement (including clause 16.4 below).

16.4 The Receiving Party may disclose any part of the Confidential Information solely to the extent that it is legally required to do so pursuant to an order of a court or arbitral tribunal of competent jurisdiction or any applicable Law or, in the case of Janssen, a competent governmental authority, or the rules of any securities exchange to which Janssen or its Affiliates may be subject or under applicable securities Laws; provided that and subject to clause 16.6 the Receiving Party shall (a) unless prohibited by Law, promptly notify the Disclosing Party prior to making such disclosure and limit such disclosure and, if permitted, provide the Disclosing Party with an opportunity to intervene to protect its Confidential Information, including an opportunity to make representations to the relevant court, arbitral tribunal, or governmental authority (as applicable) objecting to disclosure, and (b) use reasonable efforts to obtain assurances that confidential treatment will be accorded to the Confidential Information to be disclosed pursuant to this clause 16.4. Without prejudice to the generality of the foregoing, the Government Purchaser acknowledges and agrees that Janssen's Confidential Information (a) constitutes commercial, financial, scientific and/or technical information supplied to the Government Purchaser in confidence, and (b) is competitively sensitive and proprietary information of Janssen that, if disclosed or otherwise made available to the public, would result in significant competitive prejudice and undue loss to Janssen and its Affiliates. Accordingly, Janssen reserves and relies upon all of its rights under any applicable freedom of information Laws, and the Government Purchaser shall assist Janssen in protecting Janssen's Confidential Information and take all other reasonable steps to prevent disclosure of any such Confidential Information under such applicable Laws.

16.5 The obligations contained in this clause 16 shall continue for ten (10) years following the expiry or termination of this Agreement.

16.6 Neither Party shall issue any press release or make any other public statement disclosing the other Party's Confidential Information without the prior written consent of the other Party, provided that Janssen or its Affiliates may issue any press release or other public statement required under the rules of any securities exchange to which Janssen or its Affiliates may be subject or applicable securities Laws.

16.7 Janssen acknowledges and agrees that the Government Purchaser may face any of the circumstances below in which event the Government Purchaser may desire to disclose certain information regarding its Programme, the COVID Vaccine or this Agreement which may constitute Confidential Information, namely that:

(a) the Government Purchaser believes transparency as regards the Programme is important to garner public trust and confidence in and support for the Programme; so as to encourage maximum public uptake of the COVID-19 vaccines, or

(b) during the course of the Programme, the Government Purchaser considers it possible that emergency situations may arise which necessitates expeditious disclosure of Confidential Information in order to protect public safety; or

16.8 Accordingly, if the Government Purchaser believes that any of the circumstances envisioned in clause 16.7 exist, (i) the Government Purchaser shall provide notice of such circumstances to Janssen which describes the circumstances, the Government Purchaser's desired disclosures and an identification of the portion of such disclosure which constitutes Janssen's Confidential Information; and (ii) Janssen and the Government Purchaser shall generally co-operate with one another in good faith with respect reaching a mutually agreeable approach to such disclosure. As part of such cooperation, the Parties will discuss, among other things:

(a) the value of disclosure of Janssen Confidential Information toward resolution of the circumstances in clause 16.7;

(b) the commercial, regulatory, scientific, strategic or other value of the Janssen Confidential Information to Janssen, and, the extent to which, if disclosed or otherwise made available to the public, would result in significant competitive prejudice and undue loss to Janssen and its Affiliates;

(c) the extent to which similar information of other vaccine manufacturers has been disclosed (or has not been disclosed) by the Government Purchaser;

(d) the extent to which similar information has been disclosed (or has not been disclosed) by Janssen in other countries; and

(e) redaction, partial or selective disclosure (whether as to content or audience) or other mechanisms by which appropriate disclosure may considered to be made while providing reasonable assurances that confidential treatment will be accorded to the Confidential Information.

17. INDEMNIFICATION

17.1 The Government Purchaser shall indemnify and hold harmless Janssen, its affiliates, sub-contractors and sub-licensees, all of its partners and third-party contractors involved in or otherwise contracted for the design, research, development (including pre-clinical and clinical testing), manufacturing (including contract manufacturers), packaging and labelling (including warnings), procurement, storage, distribution and deployment of the COVID Vaccine, as well as its and their respective officers, directors, employees and other agents and representatives (together, the "**Indemnified Persons**") from any and all (i) losses, claims (including claims for personal injury or death), actions, liabilities, damages, judgments and awards, (ii) costs and expenses pertaining to or resulting from the defense, resolution (including settlement) or processing of any such losses, claims, actions, liabilities, damages, judgments or awards (including attorneys' and other professional advisors' fees and expenses (including taxation)), and (iii) procedural costs (including penalties, interest, fines and taxes on court ordered payments) ((i) to (iii) together, the "**Losses**") suffered or incurred by, or against, the Indemnified Persons in connection with any demands, claims, actions or proceedings of any kind:

(a) involving, relating to, or arising out of or in connection with the COVID Vaccine (including, and regardless of whether the alleged cause of the damage originates from, the design, research, development, testing, manufacture, labelling, packaging, sale, procurement, delivery, deployment, distribution, storage, administration, effects and/or use of the COVID Vaccine); and

(b) brought or initiated by or on behalf of:

(i) the Government Purchaser or any state, provincial, municipal, local or regional governments or competent public authorities within the Territory, or any of its or their respective agencies, departments, ministries, bodies, governments (local, regional or federal) or other public authorities of any kind; or

(ii) a Vaccinated Individual whose Residence is in the Territory (irrespective of the nationality, citizenship or country of origin or incorporation of such Vaccinated Individual); or

(iii) a Vaccinated Individual who has been administered the COVID Vaccine in the Territory (even if such Vaccinated Individual's Residence is not in the Territory); or

(iv) any other person in the courts of competent jurisdiction of the Territory, including within any state, province, municipality or locality thereof.

17.2 The indemnification right under clause 17.1 will not be available to the Indemnified Persons to the extent that their Losses result directly from the Adjudicated Wilful Misconduct or Adjudicated Failure to comply with cGMP of such Indemnified Persons.

17.3 If any person makes a claim or initiates a demand, claim, action or proceeding (or notifies in writing an intention to do so) against an Indemnified Person which, in the reasonable opinion of Janssen is considered likely to result in indemnification under clause 17.1 above (a "**Claim**"), Janssen shall:

(a) as soon as reasonably practicable, give written notice of the Claim to the Government Purchaser, specifying the nature of the Claim in reasonable detail (insofar as available), provided that the failure to promptly provide such notice shall not relieve the Government Purchaser of its indemnification obligations under clause 17.1; and

(b) in Janssen's sole discretion:

(i) either take such actions as it may consider reasonable and appropriate to avoid, dispute, compromise or defend the Claim (with all related costs, fees and expenses, as well as Losses, to be paid by the Government Purchaser), provided that Janssen may settle the Claim only with the prior consent of the Government Purchaser (such consent not to be unreasonably withheld, conditioned or delayed); or

(ii) require the Government Purchaser to assume (with its own counsel and at its own costs) sole control of the defence or settlement of the Claim and substitute, where possible under applicable Law, the Government Purchaser as the defendant; provided that in such case:

(1) the Government Purchaser shall reasonably take into consideration the interests (commercial, corporate, reputational or other) of Janssen and shall not conclude any agreement or make any compromise or settlement with any person in relation to such Claim without the prior written consent of Janssen (such consent not to be unreasonably conditioned, withheld or delayed); and

(2) Janssen shall have the right, but not the obligation, to participate in the defence or settlement of the Claim and to retain its own counsel in connection with such Claim; and

(3) Janssen shall provide assistance and information reasonably required by the Government Purchaser in the defense of the Claim (at the expense of the Government Purchaser), provided that (a) any information reasonably considered by Janssen as confidential or proprietary information shall be provided by it only if and when satisfactory confidentiality arrangements are put in place, and (b) under no circumstances shall Janssen provide any information (including trade secrets) which it reasonably believes would cause material harm to it or other Indemnified Persons if disclosed.

17.4 The Government Purchaser's obligation to indemnify the Indemnified Persons for Claims under clause 17.1 is not subject to a financial limitation or maximum, nor is it limited by the number of indemnifiable Claims brought against the Indemnified Persons.

17.5 It is the intention of the Government Purchaser to constitute Janssen as a trustee for and agent of the Indemnified Persons that are not party to this Agreement of the covenants of the Government Purchaser contained in clauses 17.1 to 17.4 above and the Government Purchaser agrees that Janssen may enforce the indemnity covenants of the Government Purchaser contained in clauses 17.1 to 17.4 above for and on behalf of each applicable Indemnified Person and, in such event, the Government Purchaser will not, in any

proceeding to enforce the indemnity by or on behalf of the applicable Indemnified Persons, assert any defense thereto based on the absence of authority or consideration or privity of contract and irrevocably waives the benefit of any such defense.

17.6 The Parties acknowledge and agree that the provisions of clauses 17.1 to 17.5 are reasonable and necessary to protect the legitimate interest of the Indemnified Persons. However, if any provision in clauses 17.1 to 17.5 is held to be illegal, invalid or unenforceable, in whole or in part, under any applicable Law, then such provision shall not be nullified, but the Parties shall be deemed to have agreed to such provision that conforms with the limitations imposed by applicable Law and that is as close as possible to the original intention of the Parties and has the same or as similar as possible economic effect, and such provision shall be automatically reformed accordingly.

17.7 If any payment in satisfaction of the indemnification right under clause 17.1 is liable to tax in the hands of an Indemnified Person as recipient of such payment (the "**payee**"), then the payment shall be increased by such additional amount as necessary to ensure that the payee receives a net sum equal to the sum it would have received had the payment not been liable to tax. If and to the extent the relevant tax authority subsequently determines that no liability for tax arose in respect of such payment, then the payee shall re-pay such additional amount to the payor which made the aforementioned payment in satisfaction of the indemnification right under clause 17.1.

18. TERM AND TERMINATION

18.1 To the extent that the requisite Regulatory Approval for the COVID Vaccine is discontinued, becomes invalid or is otherwise withdrawn by the Regulatory Authority, the Government Purchaser shall be entitled to cease implementation of the Programme. Such action by the Government Purchaser shall not constitute a breach of the Agreement.

18.2 Without prejudice to clause 19.3, this Agreement shall automatically expire at such time as Janssen shall have Delivered the Additional Vaccine Volume and received payment in full of the aggregate Price for the Additional Vaccine Volume by the Government Purchaser.

18.3 Without prejudice to clause 19.3, either Party may terminate this Agreement with immediate effect on notice if at any time the other Party commits a Material Breach of this Agreement and fails to remedy that breach within ninety (90) days, or, in the case of a breach by the Government Purchaser of its payment obligations under clause 10, fifteen (15) days, of that Party being notified in writing to do so.

18.4 Without prejudice to any other right under this Agreement and to clause 19.3, Janssen may terminate this Agreement with immediate effect on notice to the Government Purchaser in the following circumstances:

(a) if the Government Purchaser has not established a No Fault Compensation System in accordance with clause 4.1 by 30 April 2021; or

(b) if Janssen abandons its development program in respect of the Vaccine Candidate (including in case of inadequate safety profile); or

(c) if Janssen has not been able to obtain Regulatory Approval and the authorisation or exemption under the GMO Act referenced in 4.2(d), by 15 November 2021 (the "**Approval Long Stop Date**"); or

(d) in the circumstances set out in clause 20 (*Force Majeure*), where resuming implementation of the Agreement is considered impossible by Janssen (acting reasonably).

18.5 Without prejudice to any other right under this Agreement and to clause 19.3, the Government Purchaser may terminate this Agreement with immediate effect on notice to Janssen (such notice, the "**Termination Notice**") if and to the extent the COVID Vaccine is not safe and/or efficacious in vaccinating individuals in the Territory. If the Government Purchaser exercises its termination right under this clause 18.5, Janssen shall reimburse the Government Purchaser the following amounts:

(a) an amount corresponding to such portion of the Down Payment relating to such quantity of the Additional Vaccine Volume which has not yet been Delivered at the time of serving the Termination Notice (such amount to be calculated as follows: USD 2.50 *multiplied by* the number of non-Delivered Vaccine Doses of the Additional Vaccine Volume); and

(b) if and only if the Government Purchaser has already paid to Janssen the Price Balance in respect of any quantity of the Additional Vaccine Volume which has not yet been Delivered at the time of serving the Termination Notice, an amount corresponding to such Price Balance in respect of such quantity of non-Delivered Vaccine Doses of the Additional Vaccine Volume.

For clarity, Janssen shall under no circumstances reimburse any amount paid by the Government Purchaser under this Agreement in respect of any quantity of Vaccine Doses which have been Delivered by Janssen prior to serving of a Termination Notice.

19. EFFECTS OF TERMINATION OR EXPIRY

19.1 On termination or expiry of this Agreement, each Party shall promptly:

(a) return to the other Party all equipment, materials and property belonging to the other Party that the other Party had supplied to it in connection with the purchase of the Additional Vaccine Volume under or in connection with this Agreement;

(b) return to the other Party all documents and materials (and any copies) containing the other Party's Confidential Information;

(c) subject to clause 19.1(b), erase all the other Party's Confidential Information from its computer systems (to the extent possible); and

(d) on request, certify in writing to the other Party that it has complied with its obligations under this clause 19.1.

19.2 On termination of this Agreement, Janssen shall immediately be relieved from any outstanding obligations to make Available or Deliver the Additional Vaccine Volume, Subject to the foregoing, termination or expiry of this Agreement shall not affect any rights, remedies, obligations or liabilities of the Parties that have accrued up to the date of termination or expiry, including the right to claim damages in respect of any breach of this Agreement which existed at or before the date of termination or expiry.

19.3 Clauses 1, 6.2, 9, 10 (to the extent any payment obligations are still outstanding), 12, 14, 17 (for the period stated therein), 18, 20, 22 and 23 shall survive the termination or expiry of this Agreement.

20. FORCE MAJEURE

If and to the extent that Janssen, its Affiliates or its or their respective sub-contractors are prevented from performing any or all of Janssen's obligations under this Agreement because of any cause which arises from or is attributable to acts of regulatory or governmental authorities or entities (including embargoes, export or import restrictions, quota or other restrictions or prohibitions, or failures to grant necessary licenses or consents) or acts, events, omissions or accidents beyond the reasonable control of Janssen, its Affiliates and/or its or their subcontractors, including strikes, lock-outs or other industrial disputes (whether involving the work force of Janssen and/or its Affiliates and/or sub-contractors, of the Government Purchaser or of any Third Party), fire, storm, flood, earthquake or other acts of god or nature, disease (including SARS-CoV-2/COVID-19 or other pandemics), shortage of materials (including raw materials for the manufacture of the COVID Vaccine), unavailability of transport, interruption in electricity supply, default by suppliers, war, riot, civil commotion, malicious damage, any Law or direction issued by any judicial, arbitral, governmental, quasi-governmental or other competent institution (including the Regulatory Authority), or the inability of Janssen and/or its Affiliates to operate manufacturing or development activities due to lack of staff as a consequence of any of the foregoing, then Janssen shall be excused performance of its obligations to the extent and for the period required by such cause.

21. NOTICES

21.1 Method of service

A notice given under this Agreement by any Party to the other Party shall be in writing (which shall include e-mail), signed in manuscript by or on behalf of the Party giving it (which includes a scanned manuscript signature or, in the case of e-mail, that the message was sent from an e-mail address of the Party giving it (and which sender's e-mail address is one to which notices and other communications may also be validly delivered to that Party under this clause 21.1)), in the English language and may be either:

(a) delivered personally by hand; or

(b) if sent from within the same jurisdiction in which the recipient's address is located, then sent by first class pre-paid recorded delivery post or courier (or, if sent from outside the jurisdiction in which the recipient's address is located, then sent by international courier); or

(c) sent by e-mail,

in each case addressed as follows:

For Janssen:

Address: Janssen Pharmaceutica NV, 30 Turnhoutseweg, B-2340 Beerse

E-mail address: [redacted]

For the attention of: Legal department

Redacted by HJI
4 Sept 2023

With a copy to Janssen Pharmaceutica Pty Ltd:

Address: 2 Medical Road, Midrand, Gauteng, South Africa, 1682

E-mail address: [redacted]

For the attention of Mr Francisco Plaza Munoz

Redacted by HJI 4 Sept 2023

For the Government Purchaser:

Address: Civitas Building, 222 Thabo Sehume Street, CBD, Pretoria, 0001

E-mail address: [redacted]

For the attention of: Director General of National Department of Health

21.2 **Deemed service**

Without prejudice to any earlier time at which a notice may be actually given and received, a properly addressed notice will in any event:

(a) if personally delivered, be deemed to have been given and received upon delivery at the relevant address;

(b) if posted to an address in the same jurisdiction as that from which it was sent by first class pre-paid recorded delivery post or courier (which courier advises of delivery within two (2) Business Days), be deemed to have been given and received two (2) Business Days after the date of posting;

(c) if sent to an address in a different jurisdiction as that from which it was sent by international courier (which courier advises of delivery within seven (7) Business Days), be deemed to have been given and received seven (7) Business Days after the date of posting; or

(d) if sent by e-mail and no delivery failure is reported to or by the sender's e-mail server, be deemed to have been given and received on the date such e-mail was sent (or, if such day is not a Business Day, then the next Business Day).

21.3 **Proof of service**

In proving service, it shall be sufficient to prove that:

(a) the envelope containing the notice was addressed to the address of the relevant Party as set out in clause 21.1 (or as otherwise notified by that Party pursuant to clause 21.5) and delivered either to that address or into the custody of the postal authorities as first class pre-paid recorded delivery post or custody of the courier, or international courier firm; or

(b) the e-mail was correctly addressed and that no delivery failure was reported to or by the sender's e-mail server.

21.4 **Receipt outside business hours**

If receipt or deemed receipt of a notice occurs before 9.30 a.m. in the country of receipt on a Business Day, the notice shall be deemed to have been received at 9.30 a.m. (in the country of receipt) on that day. If deemed receipt occurs after 5.30 p.m. (in the country of receipt)

on a Business Day or on a day which is not a Business Day, the notice shall be deemed to have been received at 9.30 a.m. (in the country of receipt) on the next Business Day.

21.5 **Change of address**

Any Party to this Agreement may give at least five (5) Business Days' notice to the other Party to change its address or other details specified in clause 21.1.

22. MISCELLANEOUS

22.1 **Assignment and other dealings**

22.1.1 Other than with the written consent of Janssen, which consent will not be unreasonably withheld, the Government Purchaser may not assign, transfer, mortgage, charge, or otherwise grant any other person any interest in, the whole or any part of the benefit of, or any of its rights or obligations or interests under, this Agreement.

22.1.2 Janssen may assign, transfer, mortgage, charge or grant to any of its Affiliates any interest in, the whole or any part of the benefit of, or any of its rights or obligations or interests under, this Agreement.

22.1.3 Janssen may perform its obligations under this Agreement through any of its Affiliates, provided that Janssen remains bound by its contractual obligations and responsible for the implementation of this Agreement.

22.2 **Entire agreement**

22.2.1 This Agreement constitutes the whole agreement and understanding between the Parties relating to the subject matter of this Agreement and supersedes and extinguishes any previous agreement or arrangement between the Parties relating to the subject matter of it and excludes any representation, promise, assurance or other undertaking implied by Law, custom or course of dealing. For the avoidance of doubt, this Agreement shall not supersede or extinguish any rights or obligations of the Parties under the APA.

22.2.2 Nothing in this clause 22.2 shall limit or exclude any liability or remedy for fraud or wilful misconduct.

22.3 **Language**

This Agreement shall be executed in the English language. In the case of any translation of this Agreement, the English version of this Agreement shall prevail.

22.4 **Variation**

No amendment to or variation of this Agreement is effective unless it is in writing and signed by a duly authorized representative of each Party to this Agreement.

22.5 **Severance**

22.5.1 If any provision of this Agreement is held by any court or arbitral tribunal of competent jurisdiction to be invalid, unenforceable or illegal, in whole or in part, such provision shall apply with whatever deletion or modification is necessary so that the provision is valid, enforceable or legal and gives effect to the intention of the Parties.

22.5.2 To the extent it is not possible to delete or modify the provision, in whole or in part, under clause 22.5.1, then such provision or part of it shall, to the extent that it is illegal, invalid or unenforceable, be deemed not to form part of this Agreement and the legality, validity and enforceability of the remainder of this Agreement shall, subject to any deletion or modification made under this clause 22.5, not be affected.

22.6 **Counterparts**

This Agreement may be executed in any number of counterparts, each of which is deemed to be an original and which together have the same effect as if each Party had signed the same document. The Parties acknowledge and agree that this Agreement may be executed by electronic signature, which shall be considered as an original signature for all purposes and shall have the same force and effect as an original signature. "Electronic signature" shall include faxed versions of an original signature or electronically scanned and transmitted versions (e.g., via pdf) of an original signature or signatures affixed via e-signing platforms (such as Adobe Sign or DocuSign).

22.7 **No agency, joint venture or partnership**

Nothing contained in this Agreement shall constitute or be deemed to constitute an association, joint venture or partnership between the Parties and neither Party shall be, or be construed to be, the agent of the other Party for any purpose or to have any authority to bind or incur any liability on behalf of the other Party, save as otherwise expressly provided in this Agreement.

22.8 **Waiver**

No failure to exercise, nor any delay in exercising, any right, power, privilege or remedy under this Agreement shall in any way impair or affect the exercise of such right, power or privilege or remedy, or operate as a waiver of such right, power or privilege or remedy in whole or in part. The waiver by any Party of any of its rights or remedies arising under this Agreement or by Law shall not constitute a continuation of that or any other right or remedy. No single or partial exercise of any right, power, privilege or remedy under this Agreement shall preclude or restrict the further exercise of that or any other right, power, privilege or remedy.

22.9 **Third party rights**

Subject to the rights of Indemnified Persons under clause 17, a person who is not a Party to this Agreement shall not have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement.

22.10 **Wilful Default**

Without prejudice to any other rights or remedies Government Purchaser may have, in the event of Willful Default by Janssen of its obligations under this Agreement, Government Purchaser may bring a contractual claim for damages (including, as the case may be, a claim for refund of all or part of the Down Payments paid to Janssen) in the courts of competent jurisdiction and, in such case, nothing in this Agreement shall exclude or limit Government Purchaser's ability to request (as part of its claim for damages) to recover Down Payments which have been lost.

23. GOVERNING LAW, DISPUTE RESOLUTION AND WAIVER OF SOVEREIGN IMMUNITY

23.1 Governing law

This Agreement (including the agreement to arbitration in clause 23.2 below) and all matters relating to or in connection with it shall be governed by, and construed in accordance with, the Laws of England and Wales, without regard to any conflicts of law principles. The Parties specifically disclaim the UN Convention on Contracts for the International Sale of Goods.

23.2 Dispute Resolution

23.2.1 In the event of any contractual or non-contractual dispute, controversy or claim arising out of or in connection with this Agreement (including any question regarding its existence, validity or termination) (a "**Dispute**"), the Dispute shall be referred to and finally resolved by arbitration under the LCIA Arbitration Rules (the "**Arbitration Rules**"), which Arbitration Rules are deemed to be incorporated by reference into this clause. The number of arbitrators shall be three. Each Party shall nominate in the Request and the Response (both terms as defined in the Arbitration Rules), respectively, one co-arbitrator for appointment by the LCIA Court. If a Party fails to nominate a co-arbitrator in the Request or the Response, the selection and appointment of the co-arbitrator shall be made by the LCIA Court. The presiding arbitrator shall be jointly nominated by the two co-arbitrators for appointment by the LCIA Court. If the two co-arbitrators fail to reach agreement regarding a nomination within thirty (30) days of their appointment by the Court, the selection and appointment of the presiding arbitrator shall be made by the LCIA Court. The seat, or legal place, of arbitration shall be London, England. The language to be used in the arbitral proceedings shall be English.

23.2.2 Judgment upon the award may be entered by any court of competent jurisdiction.

23.3 Waiver of sovereign immunity

The Government Purchaser hereby expressly, unconditionally, and irrevocably waives, to the extent possible, in respect of itself and its assets, any right of immunity under the laws of any jurisdiction on the grounds of sovereignty or otherwise which may now or hereafter exist, whether immunity from service, from any legal or arbitral process, from jurisdiction of any court or arbitral tribunal, from attachment prior to judgment, in aid of execution or execution, or claim thereto, which may now or thereafter exist, and agrees not to assert any such right or claim in any legal or arbitral action or proceeding, whether in the United Kingdom or otherwise. This waiver includes but is in no way limited to waiving any right of sovereign immunity as to the Government Purchaser and any of its property, regardless of the commercial or non-commercial nature of this property, including any bank account belonging to Government Purchaser (whether held in the name of a diplomatic mission or otherwise) or bank accounts, belonging to the Government Purchaser's central bank or other monetary authority. For the avoidance of doubt, the irrevocable waiver in this clause 23.3 includes a waiver of any right of sovereign immunity in respect of pre-judgment interim relief and post-judgment execution of any arbitral award, wherever such relief or execution is sought.

[Signatures appear on the next page]

SIGNATURE PAGE TO ADVANCE PURCHASE AGREEMENT

This Agreement has been entered into on the date stated at the beginning of it.

EXECUTED by **JANSSEN**

acting by its duly authorised officer

Special Envoy for Covid-19 Vaccine

Role

Jaak Peeters

Name [redacted]

EXECUTED by **GOVERNMENT PURCHASER**

acting by its duly authorised officer

Director-General

Role

Redacted by HJI 4 Sept 2023

By signing this Signature Page you represent and warrant to Janssen that you have the requisite power and authority and the legal right to enter into this Agreement on behalf of the Government Purchaser and to bind the Government Purchaser to the terms of this Agreement.

Dr Sandile Buthelezi [redacted]

Name

EXHIBIT A

TENTATIVE AVAILABILITY SCHEDULE

Based on assumptions as at the Effective Date (certain of which are outlined below), after Regulatory Approval and subject to the conditions of the Agreement, Janssen tentatively expects to be able to make Available to the Government Purchaser allocations of the Additional Vaccine Volume as follows.

The Parties acknowledge that actual Availability of the Additional Vaccine Volume may differ from what is currently expected, as described on this **Exhibit A**, and Janssen may, after consultation with Government Purchaser as part of the operational discussion platform referred to in clause 14, amend the timelines and volumes set out in the table below.

Expected Calendar Quarter(s) of Availability	***Additional Vaccine Volume per Quarter***	***Additional Vaccine Volume Cumulative***
Quarter 3 of 2021	5 million	5 million
Quarter 4 of 2021	15 million	20 million

Notes and Assumptions:

- Commencement of Availability (and subsequent Delivery) of Additional Vaccine Volume is dependent on Regulatory Approval as well as on the local quality release of Additional Vaccine Volume by local competent authorities, and is based on current expectation as to timing of regulatory approvals globally and process and timing for local quality release of Additional Vaccine Volume by local competent authorities. Should certain jurisdictions obtain regulatory approval prior to or later than the current assumption or should the current expectations regarding process and timing for local quality release of Additional Vaccine Volume by local competent authorities prove to be incorrect, the foregoing allocation may be changed by Janssen.

- The foregoing assumes that all contemplated Janssen manufacturing capacity produces at expected volumes and that the jurisdictions of production allow free export of the Additional Vaccine Volume. Should one or more facilities (or portions thereof) fail to come online as expected or should there be any issues with export or transport, this allocation may be changed by Janssen.

- The timing reflected in the above table assumes that the Additional Vaccine Volume will be released for sale based solely on Janssen's standard requirements. If importation or sale of the Additional Vaccine Volume is subject to local release testing or other requirements that are in addition to Janssen's standard requirements, Delivery of the Additional Vaccine Volume may take longer than the Availability schedule set forth above.

- Final dose and administration schedule will be determined by reference to data from ongoing and completed clinical studies. If concentration and/or dosing and/or administration schedule change, this allocation may be changed by Janssen.

EXHIBIT B

NO FAULT COMPENSATION SYSTEM

The Government Purchaser has established and shall maintain the No Fault Compensation System in accordance with the following minimum requirements:

1 No-Fault Compensation System (also referred to in this Exhibit B as the "System"):
a. Victims should only be required to demonstrate a causal link between the COVID Vaccine and the relevant damages, without the need to prove negligence, fault or product defect.
b. Victims should be required to demonstrate causation by a preponderance of the evidence (or a similar evidentiary standard).
2 Administrative structure
a. A system should be administered by a public administrative body.
b. System should include an adequate public funding mechanism but additional financing sources can be added.
3 Governance structure
a. Administrative bodies should include representation from diverse stakeholders.
b. Decision making panels should be composed of experts with clearly defined requirements (medical, legal).
4 Covered vaccines
a. Systems should cover injuries resulting from Covid-19 vaccines. Systems may cover injuries from other classes of vaccines as well, but the funding needs to be separate for Covid-19 vaccines.
b. Applicants can be anyone who has been administered a Covid-19 vaccine in the Territory.
5 Covered damages
a. System should cover a reasonably broad class of damages, including death, injury, disability, pain and suffering, and other forms of economic and noneconomic loss resulting from the injury.
b. Minor injury and resulting damages should not be covered.
6 Compensation

a. The level of compensation offered by the System, as supplemented by other governmental arrangements (e.g., social security programs), should be sufficient to provide long-term relief to victims.
b. Compensation could be tariff-based, consistent with the level of compensation as per 6a.
7 Accessible and Efficient Procedures
a. System should use simple and easily available intake forms.
b. Bringing claims should not require legal assistance.
c. Bringing claims should be free of charge.
d. The review and decision-making process should be well-defined and easily understood by victims.
e. System should have reasonably efficient timelines for processing claims and rendering decisions.
f. System should allow victims to appeal decisions within the compensation system and finally through a court system (adequate legal remedies), with such appeal being directed against the compensation system (not against the manufacturer or any other party).
g. The Government Purchaser should implement strategies to ensure broad public awareness of their compensation system.
h.The system needs to be properly resourced (personnel, funding, organization) and have the proper infrastructure, in particular, IT, to handle the case load.
8 Transparency
a. System should include formal, well-defined transparency measures, such as mandatory annual reports and/or requirements to regularly provide public access to system information (e.g., claims received, claims excepted, and compensation amounts).

EXHIBIT C

NON-CONFORMING VACCINE VOLUME

Section 1.01. Defective COVID Vaccine. All COVID Vaccine Delivered to the Government Purchaser under this Agreement may be inspected by the Government Purchaser by means of (i) a customary visual inspection of the shipment (without opening secondary packaging) and (ii) by consulting the certificate of analysis accompanying such COVID Vaccine. If any of such inspections referenced above under (i) and (ii) reveal that any COVID Vaccine Delivered to the Government Purchaser does not meet the Specifications (any such COVID Vaccine being the "**Nonconforming COVID Vaccine**"), the Government Purchaser may reject such Nonconforming COVID Vaccine by delivering a written notice (a "**Rejection Notice**") to Janssen describing, in reasonable detail, the alleged nonconformity and, if requested by Janssen, providing sample(s) of the alleged Nonconforming COVID Vaccine. If the Government Purchaser does not deliver a Rejection Notice within (a) in the case of a visible defect, five (5) Business Days after Delivery of such COVID Vaccine or (b) in the case of a defect not detectable through initial customary visual inspection, within ten (10) Business Days after the date the Government Purchaser discovered or should have reasonably discovered such nonconformity, the received COVID Vaccine shall be deemed to be in compliance with the Specifications and accepted by the Government Purchaser.

Section 1.02. Janssen's Right to Verify Nonconforming COVID Vaccine. Following receipt of a Rejection Notice pursuant Section 1.01 above, Janssen will have ten (10) Business Days to inspect the Nonconforming COVID Vaccine and make a reasonable assessment of the alleged nonconformance, provided that the Government Purchaser has provided Janssen with appropriate sample(s) of the Nonconforming COVID Vaccine or such other reasonably available evidence Janssen may reasonably specify. If Janssen agrees that any Delivery contains Nonconforming COVID Vaccine and that such non-conformance was caused by Janssen or any of Janssen's suppliers or subcontractors, Janssen shall either (i) replace such Nonconforming COVID Vaccine as soon as commercially practicable at no additional charge to the Government Purchaser or (ii) refund the Government Purchaser the applicable Price paid by the Government Purchaser to Janssen for the Nonconforming COVID Vaccine. Any such replacement and reimbursement to which Janssen is obliged in accordance with the foregoing shall constitute Janssen's sole and exclusive liability for such Nonconforming COVID Vaccine and the Government Purchaser waives any and all other remedies it may be entitled to under applicable Laws.

Section 1.03. Disagreements Regarding Nonconforming COVID Vaccine.

(a) Independent Third Party Laboratory. If Janssen disagrees with the Government Purchaser's determination that certain COVID Vaccine Delivered is a Nonconforming COVID Vaccine, then Janssen shall promptly notify the Government Purchaser thereof and, if the Parties are unable to resolve such disagreement within a five (5) Business Days period after delivery of such notice and the Government Purchaser still alleges that such COVID Vaccine Delivered, as applicable, is Nonconforming COVID Vaccine, then sample(s) of such COVID Vaccine Delivered shall be submitted for testing to a qualified independent Third Party laboratory mutually agreed to by Janssen and the Government Purchaser ("**Third Party Lab**"), for analytical testing to verify the COVID Vaccine Delivered conformance to the Specifications.

(b) Resolution Process. The determination of such Third Party Lab with respect to all or part of such COVID Vaccine Delivered being a Nonconforming COVID Vaccine or not, shall be final and binding on the Parties, absent manifest error. All costs, fees and expenses of the Third Party Lab testing, as well as any freight and disposition costs of the COVID Vaccine and samples sent to the Third Party Lab, and related dispute resolution costs (collectively, "**Third Party Lab Fees**"), shall be paid as follows:

(i) In the event the Third Party Lab determines the COVID Vaccine Delivered not to be Nonconforming COVID Vaccine, (a) all Third Party Lab Fees shall be paid by the Government Purchaser and (b) the Government Purchaser shall accept the applicable Delivery of and, if it has not already done so, pay the applicable Price for such COVID Vaccine, as applicable.

(ii) In the event the Third Party Lab determines the COVID Vaccine Delivered to be Nonconforming COVID Vaccine and such laboratory determines that such non-conformance was caused by Janssen prior to the Delivery of the relevant COVID Vaccine to the Government Purchaser, (a) all Third Party Lab Fees shall be paid by Janssen and (b) Janssen shall, at Janssen's election, either replace such Nonconforming COVID Vaccine as soon as commercially practicable at no additional charge to the Government Purchaser or refund the Government Purchaser the applicable Price paid by the Government Purchaser to Janssen for the Nonconforming COVID Vaccine.

(iii) In the event (i) the Third Party Lab cannot determine if the COVID Vaccine Delivered is a Nonconforming COVID Vaccine, or (ii) the COVID Vaccine Delivered is a Nonconforming COVID Vaccine, but the Third Party Lab cannot determine the cause of such non-conformance; (a) all such Third Party Lab Fees shall be equally borne by the Parties and (b) the Government Purchaser shall accept the Delivery of and, if it has not already done so, pay the Price for such COVID Vaccine, as applicable.

(iv) In the event the Third Party Lab determines (i) the COVID Vaccine Delivered to be Nonconforming COVID Vaccine and (ii) such non-conformance was caused by (a) the Government Purchaser or any of the Government Purchaser's contractors, or (b) improper handling after the Delivery, then (x) all Third Party Lab Fees shall be borne by the Government Purchaser and (y) the Government Purchaser shall accept the Delivery of and, if it has not already done so, pay the Price for such COVID Vaccine, as applicable.

Section 1.04. Handling of Rejected COVID Vaccine. The Government Purchaser shall not destroy, and shall be required to keep and store in accordance with cGMP and GDP, any allegedly Nonconforming COVID Vaccine until (i) it receives written notification from Janssen that Janssen does not dispute that the COVID Vaccine Delivered is Nonconforming COVID Vaccine; (ii) following completion of the resolution process set forth in Section 1.03(b), where such COVID Vaccine Delivered is determined by the Third Party Lab to be Nonconforming COVID Vaccine and (A) it receives written notification from Janssen that Janssen does not desire return of such Nonconforming COVID Vaccine, (B) it receives written authorization from Janssen to destroy such Nonconforming COVID Vaccine, or (C) it receives no notice, authorization or other instruction from Janssen regarding such Nonconforming COVID Vaccine within ten (10) Business Days following such completion of the resolution process pursuant to Section 1.03(b); or (iii) following completion of the resolution process set forth in Section 1.03(b), where the COVID Vaccine Delivered is determined by the Third Party Lab not to be Nonconforming COVID Vaccine, it elects to do so in its sole discretion. Upon the occurrence of any of the foregoing events under (i) through (iii), the Government Purchaser shall destroy or have destroyed such Nonconforming COVID Vaccine promptly and provide Janssen with certification of such destruction. The expense of such destruction shall be borne (1) by Janssen in the event that Janssen does not dispute that the COVID Vaccine is Nonconforming COVID Vaccine or (2) in the event the Parties resort to the resolution process, by the Party responsible to pay for the Third Party Lab Fees as described in Section 1.03(b).

Section 1.05. Recalls.

(a) In the event of an actual or threatened Recall of COVID Vaccine required or recommended by a Regulatory Authority within the Territory, or if a Recall of COVID Vaccine is reasonably deemed advisable by the Government Purchaser, or jointly deemed advisable by Janssen and the Government Purchaser due to the COVID Vaccine that is subject of such Recall being determined to be a Nonconforming COVID Vaccine pursuant Sections 1.01 to 1.03 above, such

Recall shall be promptly implemented and administered by the Government Purchaser in a manner which is appropriate and reasonable under the circumstances and in conformity with applicable regulatory requirements (accepted trade practices). Janssen shall assist the Government Purchaser as requested by the Government Purchaser to ensure a timely, accurate and complete Recall. The aggregate out-of-pocket expenses of such Recall shall be borne by (i) the Government Purchaser where its acts or omissions resulted in the need for the Recall; or (ii) Janssen where its acts or omissions resulted in the need for the Recall, or (iii) equally by both Parties where each Party's acts or omissions resulted in the need for the Recall.

(b) Janssen and the Government Purchaser shall keep each other fully and promptly informed of any notification, event or other information, whether received directly or indirectly, which might reasonably affect the marketability, safety or effectiveness of COVID Vaccine or might reasonably result in a Recall of COVID Vaccine by a Regulatory Authority.

(c) In the event of any Recall, other than to the extent caused by the Government Purchaser's, the Government Purchaser Third Party's or the Government Purchaser customers' handling of the COVID Vaccine following the Delivery thereof, Janssen shall, at the election of Janssen, either (i) replace such Nonconforming COVID Vaccine subject to the Recall as soon as commercially practicable at no additional charge to the Government Purchaser or (ii) refund the Government Purchaser the applicable Price paid by the Government Purchaser to Janssen for the Nonconforming COVID Vaccine subject to a Recall.

(d) Notwithstanding the final sentence of Section 1.05(a), in the event of any Recall caused by the Government Purchaser's, the Government Purchaser Third Party's or the Government Purchaser customers' handling of the COVID Vaccines following the Delivery thereof, the Government Purchaser shall pay Janssen's reasonable out-of-pocket expenses incurred in connection with such Recall in accordance with this Section.

For the purpose of this Section 1.05, "**Recall**" means a recall, correction or market withdrawal relating to COVID Vaccine and shall include any post-sale warning or mailing of information.

EXHIBIT D

Quality Requirements

The table below defines the roles and responsibilities between Janssen and the Government Purchaser (for the purpose of this Exhibit D, the "**GP**") with respect to compliance with applicable quality assurance requirements in respect of the Additional Vaccine Volume and the COVID Vaccine.

1. Notification	**Janssen**	**GP**
Promptly notify Janssen about any regulatory inspections related to COVID Vaccine, while under its control, including observations and actions taken to mitigate those observations.		X
Promptly communicate any untoward incident that occurs after Delivery and while COVID Vaccine is under its control and that impacts COVID Vaccine safety, quality or compliance.		X
Notify Janssen of any instance of suspected counterfeit, tampered or diverted COVID Vaccine within 24h of awareness		X
2. Permits & Regulatory Requirements	**Janssen**	**GP**
Have and maintain, or ensure that its contractors have and maintain, all necessary licenses, regulatory approvals and certificates required by competent authorities to perform all activities under its control with the COVID Vaccine up until Delivery.	X	
Comply and ensure that its contractors comply with all laws, regulations and policies applicable to the activities performed under its control with COVID Vaccine up until Delivery, including Good Distribution Practices and cGMP	X	
Have and maintain, or ensure that its contractors have and maintain, all necessary licenses, regulatory approvals and certificates required by competent authorities to perform all activities under its control with the COVID Vaccine after Delivery, including but not limited to the receipt, storage, distribution, transport and handling thereof.		X
Comply and ensure that its contractors comply with all laws, regulations and policies applicable to the activities performed under its control with COVID Vaccine after Delivery, including Good Distribution Practices and cGMP		X
Ensure distribution of the COVID Vaccine from Delivery only to entities that have the required licenses, regulatory approvals and certificates as applicable.		X
Unless otherwise authorized by Janssen, ensure that from Delivery up until administration the COVID Vaccine remains in the same form of primary and/or secondary packages as originally Delivered by Janssen without altering the product, nor remove, deface, tamper the primary and/or secondary packages of the COVID Vaccine or affix any logo or words to the product or their primary and/or secondary packages that overwrite or destroy the product lot traceability and product information.		X
Do not sell, trade or donate any expired COVID Vaccine to anyone. Expired COVID Vaccine are not to be used as sales samples		X

JP SS

3. Facilities and Equipment	Janssen	GP
Ensure sufficient space, suitable and adequate premises, installations and equipment, so as to ensure proper storage and handling of the Additional Vaccine Volume according to specifications at all times. Premises and facilities must comply with all regulations for performing all agreed activities, including Good Distribution Practices.		X
4. Field Actions	**Janssen**	**GP**
Provide final decision and authority to initiate any field action.	X	
Provide all communications to the competent authority related to field actions.	X	
Assist, adhere to and execute all requested actions from Janssen in a timely manner related to field actions.		X
5. Cold Chain	**Janssen**	**GP**
Ensure that it and any and all of its government entities and contractors involved in receiving, handling, storage, distribution, delivery and similar actions with the COVID Vaccine have appropriate procedures in place (incl. training and monitoring) to effectively handle (i) cold chain products in compliance with the prescribed conditions and requirements and (ii) temperature excursions that may occur. These procedures shall include: (a) promptly upon receipt, checking the temperature datalogger accompanying each shipment of COVID Vaccine for potential temperature excursions that may occur; (b) where a temperature alarm is visible on the display of the datalogger accompanying a shipment of COVID Vaccine, ensuring a prompt download of the temperature recording and data from the datalogger (the "**Temperature Data**"); and (c) promptly report to Janssen any such temperature alarm and Temperature Data, and subsequently follow Janssen's instructions in respect to the use of the COVID Vaccine. <u>Note to Government Purchaser</u>: - the temperature datalogger will be provided by Janssen in its shipment of COVID Vaccines, and the procedures in (a) to (c) reflect actions to be taken at the moment of Delivery of the COVID Vaccine. - After Delivery, the Government Purchaser must ensure it has appropriate procedures in place to handle cold chain products and temperature excursions that may occur. The Government Purchaser shall provide to Janssen an overview of its cold chain procedures and will consider any adjustments or additions to such procedures as may be reasonably requested by Janssen as part of the operational discussion platform referred to in clause 14.		X
Ensure that any COVID Vaccine for which cold chain requirements have not been maintained or met at any point in time following Delivery are appropriately disqualified and labelled to ensure such products are not administered to individuals. Take all necessary measures to prevent diversion of disqualified COVID Vaccine, obtain and keep destruction certificates as required by applicable law,		X

provide Janssen with such destruction certificates promptly upon request by Janssen		
6. Complaint Handling	**Janssen**	**GP**
Report all the available information to Janssen within 24 hours of becoming aware of any product complaint in relation to COVID Vaccine.		X

EXECUTED by **JANSSEN**

acting by its duly authorised officer

[redacted]

Responsible Pharmacist

Redacted by HJI
4 Sept 2023

Sara Cassie

Name

EXHIBIT E

Comfort Letter

MINISTRY: HEALTH
REPUBLIC OF SOUTH AFRICA

Private Bag X399, Pretoria, 0001, 28th Floor, Civitas Building, Cnr Thabo Sehume and Struben Street, Pretoria, 0001.
Tel: +27 12 395 8086 Fax: +27 (12) 395 9165

Private Bag X9070, Cape Town, 8000, Room 413, 120 Plein Street, Cape Town, 8000.
Tel: +27 21 465 7407/8 Fax: +27 (21) 465 1575

MINISTRY: FINANCE
REPUBLIC OF SOUTH AFRICA

Private Bag X115, Pretoria, 0001 Tel: +27 12 323 8911
Fax: +27 12 323 3262

P O Box 29, Cape Town 8000 Tel +27 21 401 3700

Website : www.treasury.gov.za , email
minrec@treasury.gov.za

The Chief Executive Officer
The Johnson & Johnson Family of Companies
PO Box 273
HALFWAY HOUSE
685
South Africa

Dear Sir

RE: LETTER OF COMMITMENT TO ESTABLISH A NO-FAULT COMPENSATION SCHEME FOR ADVERSE EFFECT SUFFERED AS A RESULT OF THE ADMINISTRATION OF COVID-19 VACCINES

In respect of the Agreement for the procurement of CoVID-19 vaccines with Janssen Pharmaceutical NV, pharmaceutical companies of Johnson & Johnson ("J & J"), a key term requested by J & J is that a no-fault compensation scheme be established to address adverse events that are suffered as a result of the administration of the vaccine.

It has been noted in discussions with J & J, and acknowledged by J & J, that a no-fault compensation scheme for vaccine related adverse events does not exist in South Africa, and that the available legislative mechanisms for establishing a scheme would require some time to undertake, even if the most expeditious processes available are pursued. A scheme would not be able to be established within the timeframes desired to enter into the Agreement.

In the interim, we hereby jointly commit to take the requisite steps to establish a no-fault compensation scheme for South Africa, backed by adequate funding arrangements to cover claims and the administration of the scheme.

In this regard, we have taken into account that the establishment of this scheme is precipitated by the vaccination roll out programme in response to the COVID-19 pandemic. The purpose of this scheme would be to facilitate expeditious and easy access to compensation for persons who suffer damages as a consequence of the COVID-19 vaccine being administered.

As you are well aware, the pandemic led to a declaration of a Public Health Emergency by the World Health Organisation. Subsequently, the South African government declared a State of National Disaster in terms of the Disaster Management Act 52 of 2002 ("the DMA"). The DMA is meant to enable government to ensure an integrated and coordinated policy to manage disasters

such as the COVID-19 pandemic, focusing on reducing, mitigating and preparing rapid and effective response to them.

It is in this light that the National Department of Health and Treasury undertake to establish this scheme which shall be called the COVID-19 Vaccine Adverse Events Fund ("the Fund"). The Fund will cover injuries resulting from COVID-19 vaccines and all persons who are eligible for vaccination in accordance with the COVID-19 vaccination policy of South Africa, and are administered with a vaccine procured by Government, will be eligible to claim for severe injuries resulting from such a vaccine. This will follow a proper, lawful and efficient assessment of each claim brought against government in order to establish causality.

It is envisaged that the Fund will be established through the promulgation of Regulations under the DMA, subject to relevant processes and approvals. In the event that the State of National Disaster ceases, the Regulations would enable the Fund to remain in place for sufficient time to finalise the claims of those individuals whose vaccination doses are covered in terms of this agreement.

We further undertake that the fund will be transparent, independent, and built on public trust. In this regard, we have resolved to appoint a panel with the required expertise to oversee the proper implementation and administration of the fund. This panel will be comprised of experts the fields of medicine, actuarial science, law and psychology. The full panel and its terms of reference will be publicly announced once the Regulations are gazetted.

In line with the indemnity clause in the APA, this fund will provide protection to the manufacturing company and its associates involved in the development, manufacture, funding, procurement, distribution, and administration, from any liability (with the exception of wilful misconduct), for the period which the indemnification clause in the agreement applies.

Government will announce in the Budget Speech on Wednesday 24 February the establishment of a no-fault compensation fund to cover claims in the event of any unlikely severe vaccine injuries. Budget allocations will be announced in due course. Government will use its best efforts through necessary legislative and other processes to ensure that adequate funding will be made available to fund both the compensation awarded and the cost of administering this fund.

Yours sincerely

DR ZL MKIZE, MP
MINISTER OF HEALTH
Date: 23/02/2021

TT MBOWENI, MP
MINISTER OF FINANCE
Date: 23/2/2021