FINALMARKUP 210503

FINAL SUPPLY AGREEMENT

between

THE GOVERNMENT OF THE REPUBLIC OF SOUTH AFRICA

(acting through its National Department of Health)

and

THE BIOLOGICALS AND VACCINE INSTITUTE OF SOUTHERN AFRICA (PTY) LIMITED

DENEYS REITZ
ATTORNEYS

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1. **PARTIES**

1.1 **THE GOVERNMENT OF THE REPUBLIC OF SOUTH AFRICA (acting through its National Department of Health).**

1.2 **THE BIOLOGICALS AND VACCINE INSTITUTE OF SOUTHERN AFRICA (PTY) LIMITED** (Registration No. 1998/011727/07) a Company registered in accordance with the Company laws of the Republic of South Africa (and whose name is in the process of being changed to such other name as the Registrar of Companies may approve).

2. **PARTICIPANTS TO THIS AGREEMENT**

The DoH enters into this Agreement in its own right as principal, and also on the basis that the provisions of this Agreement shall constitute a *stipulatio alteri* for the benefit of the following Participants:

2.1 The health ministry of the provincial government of the Eastern Cape (EC);

2.2 The health ministry of the provincial government of the Northern Cape (NC);

2.3 The health ministry of the provincial government of the Western Cape (WC);

2.4 The health ministry of the provincial government of the KwaZulu-Natal (KZN);

2.5 The health ministry of the provincial government of the Free State (FS);

2.6 The health ministry of the provincial government of the Gauteng (GT);

2.7 The health ministry of the provincial government of the Mpumalanga (ML);

2.8 The health ministry of the provincial government of the Limpopo (LM);

2.9 The health ministry of the provincial government of the North West (NW);

2.10 Any other contractually autonomous national government department or autonomous governmental entity, which has been nominated in writing by the DoH as a Participant under this Agreement.

By signifying its acceptance of this Agreement to the DoH or placing an order in terms of clause 8.1 hereof on the prescribed Order Form, a Participant shall be deemed to have accepted the benefits of this Agreement and to be bound by all the terms and conditions thereof.

3. INTERPRETATION

3.1 The headnotes to the clauses of this Agreement are inserted for reference purposes only and shall in no way govern or affect the interpretation hereof.

3.2 Unless the context dictates otherwise, the expressions set forth below shall bear the following meanings and cognate expressions shall bear the meanings which correspond:

"Agreement"	this Final Supply Agreement and any schedules/annexures hereto entered into between the DoH and the Company for the supply of Vaccines;
"Business Day"	any other day than a Saturday, Sunday or an official public holiday in the Republic of South Africa, as defined in the Public Holidays Act,

	1994, or any successor Act;
"Company"	The Biologicals and Vaccine Institute of Southern Africa (Pty) Limited (Registration Number 1998/011727/07) a company registered in accordance with the company laws of the Republic of South Africa (and whose name is in the process of being changed to such other name as the Registrar of Companies may approve);
"DoH"	the Government of the Republic of South Africa (acting through its National Department of Health) represented herein by the Director General of the Department of Health in his capacity as the accounting officer of the said department as contemplated in Section 36 of the Public Finance Management Act 1 of 1999;
"EPI"	The Expanded Programme on Immunisation as put into practice by the DoH;
"Freeze Watches"	Freeze watch indicator 0°C – An irreversible temperature indicator that records if a product has been exposed to freezing temperatures. If the indicator is exposed to temperatures below 0° for more than an hour, the vial bursts and releases a

	coloured liquid, staining the white backing card;
"GAVI"	Global Alliance for Vaccines and Immunisations;
"CCM cards / 3M Monitors Cards" "Monitor Card(s)"	Vaccine cold chain monitor card – This indicator changes irreversibly from white to blue if exposed to temperatures higher than +10°C and +34°C. This card is packaged with vaccine (1/2000 doses) to monitor storage conditions in transit and in storage;
"Order Form(s)"	An official written or electronic order issued by the DoH or a Participant for the supply of Vaccines;
"PAHO"	Pan American Health Organisation;
"Participant/s"	One or more of the provincial government health ministries, contractually autonomous national government departments or governmental entities referred to in clause 2 hereof, who participate in the purchasing programme constituted by this Agreement on the basis of having signified to the DoH that it/they accept the benefit of the *stipulatio alteri* referred to in

	clause 2 hereof or who accept the benefit of such *stipulatio alteri* by completing and lodging with the Company a written or electronic Order Form as contemplated in clause 8.1 for the purchase of Vaccines on the terms and conditions of this Agreement. Each Participant (after acceptance of the *stipulatio*) shall be bound under this Agreement as if it were the DoH as defined herein;
"Parties"	the parties to this Agreement, namely, the Company and the DoH, and to the extent that any of the entities nominated in clause 2 have accepted the benefit of the stipulation in its/their favour as contemplated in clause 2, such Participant;
"Prices"	the purchase prices at which Vaccines will be supplied by the Company to the DoH and/or Participants as referred to in clause 10; the initial prices are set out in Schedule 2A of this Agreement;
"Provincial Facility"	Any provincial health facility (depot, hospital, health centre, clinic etc.) specified by the

	relevant Participant to which Vaccines are to be delivered;
"Shareholders Agreement"	The shareholders agreement to be entered into prior to or simultaneously herewith between the South African Government, the Company and Biovac Consortium (Pty) Limited, registration number 2001/010439/07, being the agreement to which this Agreement is annexed as Schedule 3;
"Signature Date"	the date of last signature hereof;
"Suppliers"	the suppliers of the Company from time to time, including but not limited to: 1 Aventis Pasteur Merieux; 2 BioFarma 3 SSI (Statens Serum Institut-Denmark) 4 Heber Biotec 5 Cheil 6 Chiron
"UNICEF"	The United Nations Children's Fund;
"Vaccines"	The EPI Vaccines as more fully set out in schedule 1 to this Agreement, as amended and/or extended or modified from time to time in accordance with the provisions of clause 7.2;
"Vaccine Vial Monitor" ("VVM")	A vaccine vial monitor which is a label made of

	heat-sensitive material which is placed on a vaccine vial to register heat exposure over time;
"WHO"	World Health Organisation.

3.3 Unless the context dictates otherwise, an expression which denotes any gender includes both of the others, and a reference to a natural person includes an artificial person, and the singular includes the plural, and vice versa in each case.

3.4 The headings herein are for guidance and convenience only and are not, and shall not, be interpreted as a part of this Agreement.

3.5 If any provision in a definition is a substantive provision conferring rights or imposing obligations on any Party then, notwithstanding that such provision is only contained in the relevant definition, effect shall be given thereto as if such provision were a substantive provision in the body of the Agreement.

3.6 The rule of construction that the contract shall be interpreted against the Party responsible for the drafting or preparation of the Agreement, shall not apply.

3.7 The use of the word "*including*" followed by a specific example or examples shall not be construed as limiting the meaning of the general wording preceding it and the *eiusdem generis* shall not be applied in the interpretation of such general wording or such specific example or examples.

4. APPOINTMENT

4.1 The DoH hereby appoints the Company to supply Vaccines in the Republic of South Africa to the DoH and/or any Participant, for the period of and subject to the terms and conditions contained in this Agreement.

4.2 Subject to the provisions of clause 9.4 in terms of which Vaccines may be sourced from another supplier/s in defined circumstances, the DoH and any Participant(s) undertake to source all of its/their Vaccine requirements from the Company as preferred supplier.

5. CONDITIONS PRECEDENT

5.1 Notwithstanding conclusion of this Agreement in writing between the DoH and the Company, this Agreement is entirely subject to the signature of the Shareholders Agreement by the parties thereto and the said Shareholders Agreement becoming unconditional in accordance with its terms. The operation of this Agreement shall accordingly be suspended until the happening of both those events.

5.2 The Parties shall use their best endeavours to procure the fulfilment of the conditions precedent, referred to in clause 5.1 hereof as soon as reasonably possible after the Signature Date. If all of the said conditions precedent are not fulfilled by 30 June 2003 (or such extended date as the Parties may agree in writing), this Agreement (save for clauses which are expressly stated to survive the termination of this Agreement) shall be of no force or effect and no Party shall have any claim against any other Party for anything done hereunder or arising hereout.

6. PERIOD

This Agreement shall commence on 1 January 2004 and shall continue (subject to the provisions for earlier termination contained in clause 19 hereof) for a period of 4 (four) years, terminating on 31 December 2007. To the extent that the date in 5.2 is extended by mutual agreement between the Parties beyond 30 June 2003, the Parties agree that the period of this Agreement shall be extended by one month for every month (or part thereof) after 30 June 2003 that the date referred to in 5.2 hereof is so extended by agreement between the Parties.

7. VACCINES

7.1 The Vaccines are the EPI Vaccines, which are listed in Schedule 1 of this Agreement.

7.2 Schedule 1 encompasses the range of the DoH's EPI vaccine requirements as at the Signature Date. The provisions of this Agreement shall however be extended to any additions to the DoH's EPI programme from time to time, provided that at least 9 months notice in writing is given to the Company by the DoH of such addition to Schedule 1. Similarly, DoH shall give the Company at least 9 months notice in writing of any Vaccine which it intends removing from its EPI programme and hence from Schedule 1.

7.3 Any order placed with an alternative supplier in the circumstances contemplated in 9.4 shall be fully executed notwithstanding that prior to full

execution of the order concerned, the Company regains its capacity to supply the vaccine which is the subject matter of that order.

8. **ORDERS**

8.1 Vaccines shall be delivered only upon receipt of a written or electronic Order Form from the DoH and/or Participant concerned.

8.2 Orders shall be placed directly with the Company by the DoH or the Provincial Medical Supply Depot of the Participant concerned, and invoices and accounts shall be rendered directly to the purchasing office of the DoH or the Participant concerned, as the case may be.

9. **QUANTITIES**

9.1 The Company shall hold stocks sufficient to supply the requirements of DoH and/or Participants in terms of the Estimate contemplated in clause 9.4.

9.2 Orders placed by the DoH through its State medical supply depots or by Participants through provincial medical supply depots will be supplied in multiples of the smallest pack size available for the vaccine in question, unless expressly otherwise requested in the Order Form.

9.3 Orders placed by Participants for direct delivery must have a minimum monetary value of R1 000.

9.4 The DoH gives no undertaking in terms of the quantities of Vaccines to be ordered by the DoH or Participants from the Company. However, the DoH and Participant/s agree that they will purchase all their EPI requirements from the Company for the duration of this Agreement. The DoH and/or the Participants undertake to furnish the Company with an estimate during September of each year, of the quantities of Vaccines required to be ordered by the DoH or Participants from the Company for the ensuing twelve month period (the "Estimate"). To the extent that the quantity of Vaccines ordered by the DoH and/or Participants exceeds the Estimate by more than 20% in the 12 month period to which the Estimate relates, and the Company cannot supply such excess, the DoH and/or any Participant shall be entitled to purchase such excess directly from any other supplier of Vaccines, provided that in that event the DoH and/or Participant/s shall have no claim against the Company in respect of the increased cost of acquiring such excess Vaccine requirements from the alternative source. To the extent that the quantity ordered by the DoH and/or Participant/s falls within the Estimate and the Company cannot supply such quantity, the DoH and/or Participant/s shall be entitled to purchase such excess directly from any other supplier of Vaccines, and the Company shall be obliged to reimburse the DoH and/or Participant/s concerned with the difference in the cost of acquiring such Vaccines from the alternative supplier which would not have been payable if the Company had been in a position to supply in terms of the Estimate. The increased costs, of acquiring such Vaccines from an alternative supplier, shall be paid to the DoH and/or Participant/s, as the case may be, immediately upon verification of same.

10. PRICING

10.1 The Company will supply the Vaccines to the DoH and/or Participant/s at the prices more fully set out in Schedule 2 of this Agreement under the column "**SELLING PRICE IN FOREIGN CURRENCY PER DOSE**", adjusted (to the extent necessary) in accordance with the remaining provisions of this clause 10.

10.2 The price at which the Vaccines are supplied to DoH and/or Participant/s shall not exceed the prices stipulated in Schedule 2 under the heading "**SELLING PRICE IN FOREIGN CURRENCY PER DOSE**". The selling prices referred to in Schedule 2 represent maximum prices after inclusion of the Company's mark-up as stipulated in Schedule 2 and are not inclusive of VAT.

10.3 The Company undertakes throughout the duration of this Agreement to use its best endeavours to source Vaccines from suppliers at the most competitive prices, and to the extent that it succeeds in acquiring Vaccines at a price lower than the maximum price stipulated in Schedule 2 (adjusted in accordance with the remaining provisions of this clause 10), the benefit of such lower costs shall immediately be passed through to the DoH and/or the Participant/s, at all times.

10.4 Provided that exchange rates remain within a band of 7,5% (seven comma five percent) either side of the prevailing rate of exchange as at the commencement of that quarter (the "Fifteen Percent Band"), prices will be adjusted in accordance with variations in the rate of exchange once every

quarter (such quarters commencing 1 January 2004). Should the rate of exchange exceed or fall below the respective ceiling or floor levels of the applicable Fifteen Percent Band in a quarter, prices will be adjusted in accordance with the first change in the rate of exchange exceeding or falling below their respective ceiling or floor levels of the Fifteen Percent Band relative to that quarter, and shall remain fixed at that rate for the remainder of that quarter.

10.5 Adjustments to the price for rate of exchange variations during the subsistence of this Agreement will be calculated by using the base rate as set out in Schedule SA 2 and the spot rate of exchange as issued by Standard Bank of South Africa Limited at 12h00 using the following dates:

Dates to be used by the Company	Dates documentation for adjustment must be delivered to DoH	Dates from which new calculated prices will become effective	Date until which new calculated price will be effective
1 January 2004	15 January 2004	1 January 2004	31 March 2004
1 April 2004	15 April 2004	1 April 2004	30 June 2004
1 July 2004	15 July 2004	1 July 2004	30 September 2004
1 October 2004	15 October 2004	1 October 2004	31 December 2004
1 January 2005	15 January 2005	1 January 2005	31 March 2005
1 April 2005	15 April 2005	1 April 2005	30 June 2005
1 July 2005	15 July 2005	1 July 2005	30 September 2005
1 October 2005	15 October 2005	1 October 2005	31 December 2005
1 January 2006	15 January 2006	1 January 2006	31 March 2006
1 April 2006	15 April 2006	1 April 2006	30 June 2006
1 July 2006	15 July 2006	1 July 2006	30 September 2006
1 October 2006	15 October 2006	1October 2006	31 December 2006
1 January 2007	15 January 2007	1 January 2007	31 March 2007
1 April 2007	15 April 2007	1 April 2007	30 June 2007
1 July 2007	15 July 2007	1 July 2007	30 September 2007
1 October 2007	15 October 2007	1 October 2007	31 December 2007

10.6 Notwithstanding the provisions of clause 10, DoH shall be entitled to require the Company to obtain appropriate forward cover in respect of import of the Vaccines in order to fix the exchange rate from time to time. The cost of the cover shall be borne by DoH.

10.7 To the extent that there is any addition to the EPI Schedule on the basis contemplated in clause 7.2, the initial price of each vaccine added to the EPI Schedule will be benchmarked against the lowest effective cost of UNICEF, PAHO and GAVI prices for similar quantities of the same vaccine as at the date that the vaccine in question is added to the EPI Schedule.

11. DELIVERY

11.1 Delivery of the Vaccines shall be made to destinations in the Republic of South Africa in accordance with the instructions appearing on the official Order Forms emanating from the Participants.

11.2 Delivery must conform to cold chain distribution requirements, where applicable, as contemplated in clauses 14.2 and 15 of this Agreement.

11.3 All deliveries must be accompanied by a delivery note stating the official order number against which the delivery has been effected.

11.4 The maximum lead time for deliveries shall be 28 calendar days from receipt of the Order Form by the Company. However, if an item which is ordered in terms of this Agreement is in stock the Company must deliver such item within 7 Business Days of the date of receipt of the official Order Form from

the DoH or the Participant concerned.

11.5 The Company must adhere strictly to the delivery periods stipulated for the Vaccines.

11.6 If the maximum lead time referred to in 11.4 (or as otherwise agreed in writing) is exceeded, the DoH or any Participant/s shall without cancelling this Agreement, be entitled forthwith to purchase Vaccines of a similar quality and up to the same quantity in substitution of the Vaccines not supplied in conformity with clause 11.4 of this Agreement and to return any Vaccines delivered late at the Company's expense and risk.

11.7 The Company shall bear any adverse difference in price of the Vaccines referred to in clause 11.6 plus any other damages which may be suffered by the DoH which shall be paid by the Company to the DoH immediately on demand or the DoH may deduct such amounts from moneys (if any) otherwise payable to the Company in respect of Vaccines supplied or to be supplied under this Agreement.

11.8 The instructions appearing on the official Order Form regarding the supply, despatch and submission of invoices must be strictly adhered to.

11.9 The Company is responsible for the delivery and cost of delivery of all the Vaccines, as and when ordered.

11.10 No penalty or damages shall be claimed in respect of any period of delay due to batch failures, a state of war, sanctions, country-wide general strikes (but

not strikes confined to the Company only), damage to machinery as a result of accidents, fire, flood or tempest or act of God, which could not be foreseen or overcome by the Company, or to any act or omission on the part of persons acting in any capacity on behalf of the DoH.

11.11 If, for any reason, Vaccines are recalled from the DoH or a Participant, the Company must promptly specify how this is to be achieved and shall bear all costs associated with return delivery. The Company shall be obliged to replace such returned stocks at no charge, with similar Vaccines of good potency and content.

12. BARCODES

It is a specific condition of this Agreement that the packaging of all products supplied to the DoH or Participant/s must include a barcode (number plus symbology). Both the outer case and specification pack must be marked with the appropriate number and symbology. The European Article Numbering Code 13 (EAN 13) is currently required. The DoH reserves the right to upgrade this to EAN 128 or other suitable portable data file (PDF).

13. PAYMENT FOR VACCINES

Payment will normally be effected within 30 days of receipt of all the required documentation, which should be correct in every respect.

14. SPECIFIC CONDITIONS

14.1 The Company shall notify in writing the applicable competent body under the Medicines and Related Substances Control Act 1965 (Act 101 of 1965) as amended or substituted from time to time, of the release of each and every batch of Vaccines after the following has been achieved:

14.1.1 the Company has ensured that the batch complies with all the lot release requirements as per the Application for Registration of a Medicine (MBRI) requirements in terms of the Medicines and Related Substances Control Act, 1965;

14.1.2 after importation and BEFORE delivery, the Company has submitted the Vaccine to the National Control Laboratory (or its successor in function), for purposes of confirmation of identity and potency, at the following address:

National Control Laboratory
Swot Street
Faculty of Medicine
University of the Free State
BLOEMFONTEIN
FOR ATTENTION: Head of Laboratory (or his successor in office/function)
Tel: (051) 401-3015
Fax: (051) 401-3404

14.2 It is a specific condition of this Agreement in respect of the cold chain monitoring process, that all shipments of Vaccines must include 3M Monitors (or similar WHO approved mechanism) and where appropriate, Freeze Watches.

14.3 Vaccines are to be shipped in insulated containers each containing sufficient ice packs or dry ice to maintain the cold temperatures, but which will not freeze those Vaccines which are freeze sensitive.

14.3.1 Each insulated shipping container must be clearly labelled to indicate that the contents are perishable. The recommended storage temperature range must also be on the outside of each insulated container and must clearly state whether contents should be frozen or not frozen.

14.3.2 Vaccines which may not be frozen must contain both Freeze Watches (or similar WHO approved mechanism) and 3M Monitors in each insulated container. The number of Freeze Watches and /or 3M Monitors per insulated container must comply with the WHO recommendations. All the above mentioned Monitor Cards must be completed with the relevant details and activated at source.

14.3.3 For freeze-dried Vaccines, suitable quantities of the diluent (reconstituting fluid) must be supplied in separate shipping containers, if applicable.

14.3.4 One activated CCM must be packed with each consignment for delivery of the Vaccine(s) containing 2 000 doses of Vaccine or more in one container, to a Provincial Facility.

14.4 Should the CCMs indicate a break in the cold chain to the first delivery point from the Company, the vaccine must be removed/collected by the Company

at the Company's cost.

14.5 Quantities delivered must not exceed the ordered quantity. Any over-supply will be returned to the Company for the Company's account.

15. VACCINE VIAL MONITOR(S)

15.1 It is a specific condition of tender in respect of the Cold Chain Monitoring Process that all vials of oral Polio Vaccine must be fitted with Vaccine Vial Monitors, according to WHO standards.

15.2 Should Vaccine Vial Monitors be developed and approved by WHO for other Vaccines, the provisions of this clause 15 will also apply to those Vaccines when these become approved and available.

16. PACKAGING AND LABELLING

16.1 Labels and package inserts for Vaccines intended for humans, must comply with the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), general regulations No. 9 and 10.

16.2 Unless otherwise specifically provided for in this Agreement, the Company is responsible for packing the Vaccines at its own cost and in such a manner as to ensure no loss or damage in transit.

16.3 Unless otherwise agreed by the Parties no charge shall be allowed for packing material or containers and such material or containers shall not be returned to

the Company.

17. **SHELF-LIFE**

17.1 Upon delivery all Vaccines must have at least 12 months of shelf-life before the expiry date. The Company may make written applications to deliver Vaccines with a shorter shelf-life, provided such applications are accompanied by an undertaking that such short-dated Vaccines will be unconditionally replaced before or after expiry and that such applications are approved before execution of the orders.

17.2 Any delivery of short-dated vaccines without prior written approval will be subject to clause 17.1 above and the calculated balance (short dated stock) of any order will be returned to the supplier at his/her cost and a 5% administration fee.

17.3 Such written application must include an undertaking by the Company to apply the following discount formula when supplying short dated Vaccines

A=2 (12 – months to date of expiry) % X consignment value of short dated Vaccines. Therefore, amount to be received is: Consignment value – A, where A is the discount formula.

17.4 Any Participant may, in its unfettered discretion, decline written applications by the Company to deliver Vaccines with a shelf life of less than 12 months.

18. **MASS CAMPAIGNS**

Where the DoH has formal plans to embark on mass campaigns in respect of any of the Vaccines the Company will be afforded 9 months prior written notice in order to comply with any delivery obligations.

19. TERMINATION FOR BREACH

Should any Party breach any material provision of this Agreement and fail to remedy such breach within 21 (twenty one) days after receiving written notice requiring such remedy from any Party aggrieved thereby, then the Party giving such notice shall by further written notice be entitled, without prejudice to its other rights in law including any right to claim damages, to cancel this Agreement or to claim immediate specific performance of all of the defaulting Party's obligations whether or not otherwise then due for performance. The Company agrees that any breach of this Agreement by the Company shall be rebuttably presumed to be a material breach of the Agreement, and the onus of proving that such breach is not of a material nature shall at all times be borne by the Company.

20. DISPUTE RESOLUTION

20.1 Any dispute between the Parties in regard to :

20.1.1 the interpretation of;

20.1.2 the effect of;

20.1.3 the respective rights of the Parties and their respective obligations hereunder;

20.1.4 a breach of;

20.1.5 any matter arising out of:

20.1.6 the termination of; and/or

20.1.7 the rectification of;

this Agreement shall in the first instance be referred for consideration and possible resolution to a representative of each Party (designated as such by that Party in writing, and who shall be duly authorised to act in its place in that matter).

20.2 Should the officers referred to in clause 20.1 not be able to resolve the dispute within 7 Business Days of it being referred to them, then they shall by agreement, appoint a third party to act as a mediator, and not as an arbitrator, to mediate in the resolution of the dispute on a non-binding basis. Should they not be able to agree on the mediator, then the mediator shall be selected by the Chairman for the time being of the Arbitration Foundation of Southern Africa ("AFSA").

20.3 Should the mediation referred to in clause 20.21 fail to resolve the dispute within 7 Business dDays (or such longer period as the Parties may agree in writing) after the appointment of the mediator in terms of clause 20.21, then either Party shall have the right to institute legal proceedings against the other in an appropriate court of law.~~require that the dispute be referred to arbitration~~

and that Party shall notify the other Party in writing identifying the disputes and setting out the relief required.

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20.4Any dispute referred to in clause 20.1, shall be submitted to and determined by arbitration with AFSA rules ("the rules"). Such arbitration shall be held in Sandton unless otherwise agreed and shall be held in a summary manner with a view of it being completed as soon as possible.

20.5There shall be one arbitrator, who shall be, if the question in issue is :

20.5.1primarily an accounting matter, an independent chartered accountant of not less than 10 years standing; and

20.5.2primarily a legal matter, a practising Senior Counsel or Commercial attorney of not less than 10 years standing; and

20.5.3any other matter, a suitably qualified person.

20.6The appointment of the arbitrator shall be agreed upon between the Parties, but failing agreement between them within a period of 14 days after the arbitration has been demanded by either of the Parties by notice in writing to the other in terms of clause 20.1, either of the Parties shall be entitled to request the Chairman for the time being of AFSA to make an appointment of the arbitrator who, in making the appointment, shall have regard to the nature of the dispute, and shall have regard to the Parties' requirement of a speedy arbitration.

~~20.7The arbitrator shall have powers conferred upon an arbitrator under the rules.~~

~~20.8The decision resulting from such arbitration shall be made by the arbitrator and shall be final and binding on the Parties, and may be made an order of any court of competent jurisdiction. Each of the Parties hereby submits itself to the Division of the High Court of South Africa in the area in which the arbitration is held should the other Party wish to make the arbitrator's decision an order of that court.~~

~~20.9~~20.4 Mediation Pproceedings are to be held in camera and are confidential.

~~20.10~~20.5 The provisions of this clause 20 shall not preclude ~~any other~~ Party from access to an appropriate court of law for :

~~20.10.1~~20.5.1 interim relief in the form of an interdict, mandamus or order for specific performance pending the outcome of mediation~~an arbitration~~ in terms hereof~~, or in respect of such arbitration or expert determination, as the case may be~~;

~~20.10.2~~20.5.2 any other form of relief on the basis of facts which are not disputed~~, provided that if a *bona fide* dispute arises in the course of the proceedings, they shall be stayed pending arbitration on the dispute in terms hereof~~; or

~~20.10.3~~20.5.3 an order for the payment of liquidated damages on the basis of facts which are not *bona fide* in dispute at the commencement of such proceedings.

20.1120.6 The provisions of this clause 20 shall survive the invalidity and/or termination from whatever cause arising out of any or all the terms of this Agreement.

20.1220.7 The aforegoing provisions of this clause 20 shall not preclude the bringing of any proceedings by a Party in a court having jurisdiction, for urgent relief by way of interdict pending mediationarbitration in terms of this clause 20.2.

21. COMPLAINTS BY PARTICIPANTS

21.1 Any Participant having a complaint in regard to the supply of Vaccines, other than non-supply as contemplated in clause 11.6, under this Agreement by the Company shall not take action under the dispute resolution provisions of this Agreement as contained in clause 20, without first having advised the DoH of its complaint, in writing, and having consulted with the DoH with regard to ways of addressing the complaint. If a Participant has notified the DoH in writing of such complaint and the complaint in question has not been addressed to the satisfaction of the Participant concerned within 21 calendar days of such notification to the DoH, the Participant shall be entitled to pursue its remedies in terms of clause 20 of this Agreement without further reference to the DoH.

21.2 Should any complaints in regard to the supply of Vaccines under this Agreement by the Company be received by the DoH, the Company undertakes to respond fully within 14 (fourteen) days of receipt of any query directed to it by the DoH in connection with such complaint.

22. **GOVERNING LAW**

22.1 This Agreement shall be governed, interpreted and implemented according to the laws of the Republic of South Africa.

22.2 Subject to the provisions of clause 20, each of the Parties hereby submits and consents to the non-exclusive jurisdiction of the Transvaal Provincial Division of the High Court of South Africa in regard to any proceedings which may at any time be instituted against it by the other Party in respect of any matter directly or indirectly arising from this Agreement or its interpretation.

23. **SEVERABILITY**

Each provision in this Agreement is severable from all others, notwithstanding the manner in which they may be linked together or grouped grammatically, and if in terms of any judgment or order, any provision, phrase, sentence, paragraph or clause is found to be defective or unenforceable for any reason, the remaining provisions, phrases, sentences, paragraphs and clauses shall nevertheless continue to be of full force. In particular, and without limiting the generality of the aforegoing, the Parties hereto acknowledge their intention to continue to be bound by this Agreement, for the period of the Agreement, notwithstanding that any provision may be found to be unenforceable or void or voidable, in which event the provision concerned shall be severed from the other provisions, each of which shall continue to be of full force.

24. **GENERAL**

24.1 This document constitutes the sole record of the Agreement between the Parties, and replaces all previous agreements between the Parties, in regard to the subject matter thereof and no amendment, variation or consensual cancellation hereof shall be of any force or effect unless in writing and signed by all the Parties.

24.2 The provisions of the State Tender Board General Conditions and Procedures (ST36) shall apply to this Agreement as if they had been incorporated herein, provided that where there is a conflict with the provisions of this Agreement and ST36 expressly or by necessary implication, the provisions of this Agreement shall prevail.

24.3 The Parties specifically agree that the provisions of the National Industrial Participation Programme (ST18) shall not apply to the Company, or to this Agreement.

24.4 No Party shall be bound by any express or implied term, representation, warranty, promise or the like, not recorded herein.

24.5 No indulgence by any Party hereto to any other Party, or failure strictly to enforce the terms hereof, shall be construed as a waiver or be capable of founding an estoppel.

24.6 The Parties undertake at all times to do all such things, to perform all such acts and to take all such steps and to procure the doing of all such things, the performance of all such actions and the taking of all such steps as may be

open to them and necessary for or incidental to the putting into effect or maintenance of the terms, conditions and import of this Agreement and furthermore to act in good faith towards each other and to co-operate with each other to the fullest extent.

24.7 Each Party hereby agrees to waive any right, which he may have to rely on for non-performance of any obligation under the lack of authority of any signatory who has purported to sign this Agreement on his behalf.

25. DOMICILIUM

25.1 The Parties hereto choose as their *domicilia citandi et executandi* for all purposes of and in connection with this Agreement the addresses following :

25.2 The DoH : c/o The Accounting Officer, National Department of Health
Room 1718
Hallmark Building
Proes Street
Pretoria
Private Bag X828
Pretoria

Telefax:

25.3 The Company: c/o Selwyn Kahanovitz
1 Manchester Road,
Wadeville, 1428
P O Box 14374
Wadeville, 1422

Telefax: (011) 827-8688

25.4 Any Party hereto shall be entitled to change its *domicilium* from time to time, provided that any new *domicilium* so selected shall be an address other than a

box number, and any such change shall only be effective upon receipt of notice in writing by all the other Parties of such change.

25.5 All notices, demands, communications, legal process or payments intended for a Party shall be given, made or served at such party's *domicilium* for the time being.

25.6 A notice sent by one Party to another Party shall be deemed to be received :

25.6.1 on the same day, if delivered by hand;

25.6.2 on the same day, if sent by telex or telefax;

25.6.3 on the recorded date of delivery.

25.7 Notwithstanding anything to the contrary herein contained a written notice or communication actually received by a Party shall be an adequate written notice or communication to it notwithstanding that it was not sent to or delivered at its chosen *domicilium*.

THUS DONE and SIGNED at ..... on this the ..... day of ..... 2003.

For and on behalf of
THE GOVERNMENT OF THE REPUBLIC OF SOUTH AFRICA (acting through its National Department of Health)

_____
who warrants his authority hereto

THUS DONE and SIGNED at ..... on this the ..... day of ..... 2003.

For and on behalf of
THE BIOLOGICALS AND VACCINE INSTITUTE OF SOUTHERN AFRICA (PTY) LIMITED

By: ……..

_____
who warrants his authority hereto

SCHEDULE SA 1

THE VACCINES

BACILLUS CALMETTE-GUERIN FOR INTRADERMAL INJECTION	BCG	20 dose vial + Diluent
DIPHTHERIA – and TETANUS TOXOID adsorbed	DT	10 ml vial
DIPHTHERIA – TETANUS TOXOID and BORDETELLA PERTUSSIS (wholecell inactivated), adsorbed	DTP	10 ml vial
HEPATITIS B for PAEDIATRIC AND NEONATAL USE	Hep B	10 dose vial
HEPATITIS B for PAEDIATRIC AND NEONATAL USE	Hep B	1 dose vial
HEPATITIS B for ADULT USE	Hep B	1 dose vial
MEASLES , LIVE ATTENUATED VIRUS		1 dose vial + diluent
MEASLES , LIVE ATTENUATED VIRUS		10 dose vial + diluent
POLIOMYELITIS TRIVALENT ORAL		10 dose plastic dropper bottle / tube
TETANUS TOXOID adsorbed	TT	10 ml vial
COMBINED DIPTHERIA, PERTUSSIS, TETANUS AND HAEMOPHILUS INFLUENZAE TYPE B	DTP and HiB	1 DOSE PRESENTATION OF THE LYOPHILISED CONJUGATE HiB VACCINE PLUS A 1 DOSE PRESENTATION OF THE DTP FOR RECONSTITUTION

COMBINED DIPTHERIA, PERTUSSIS, TETANUS AND HAEMOPHILUS INFLUENZAE TYPE B	DTP and HiB	10 DOSE PRESENTATION OF THE LYOPHILISED CONJUGATE HiB VACCINE PLUS A 10 DOSE PRESENTATION OF THE DTP FOR RECONSTITUTION

SCHEDULE SA 2 (Page 1 of 3 pages)

(COST IN ~~(~~FOREIGN CURRENCY PER DOSE)

Product	Company	Status		Quantity		2004	2005	2006	2007
DPT	Aventis	Finished Product	20 or 10	60000	Euro	0.1630	0.2321	0.2525	0.2652
DPT	Biofarma	Finished Product	10	60000	US$	0.1084	0.1084	0.1198	0.1198
DPT	Biofarma	Bulk	20	60000	US$	0.1305	0.1320	0.1473	0.1489
DT	Aventis	Finished Product	20 or 10	110000	Euro	0.1110	0.1479	0.1607	0.1692
DT	Biofarma	Finished Product	10	110000	US$	0.0804	0.0804	0.0876	0.0876
DT	Biofarma	Bulk	20	110000	US$	0.0791	0.0806	0.0886	0.0902
TT	Aventis	Finished Product	20 or 10	290000	Euro	0.1150	0.1670	0.1820	0.1910
TT	Biofarma	Finished Product	20	290000	US$	0.0489	0.0489	0.0518	0.0518
TT	Biofarma	Bulk	20	290000	US$	0.0475	0.0490	0.0529	0.0546
DTPHib	Aventis	Finished Product	10	262250	Euro	2.2475	2.3593	2.4772	2.6013
DTPHib	Aventis	Finished Product	1	897000	Euro	2.6242	2.7553	2.8934	3.0378
HBV ASD	Heber Biotec	Finished Product	1	45755	US$	1.5645	1.6427	1.7249	1.8111
HBV PMD	Heber Biotec	Finished Product	10	375775	US$	0.4515	0.4741	0.4978	0.5227
HBV PSD	Heber Biotec	Finished Product	1	169300	US$	0.9240	0.9702	1.0187	1.0696
HBV ASD	Cheil Jedang	Finished Product	1	45755	US$	0.7000	0.7000	0.7000	0.7000
HBV PMD	Cheil Jedang	Finished Product	10	375775	US$	0.2370	0.2370	0.2370	0.2370
HBV PSD	Cheil Jedang	Finished Product	1	169300	US$	0.5100	0.5100	0.5100	0.5100
HBV ASD	Heber Biotec	Bulk	1	45755	US$	0.5682	0.5966	0.6264	0.6578
HBV PMD	Heber Biotec	Bulk	10	375775	US$	0.4255	0.4468	0.4692	0.4926
HBV PSD	Heber Biotec	Bulk	1	169300	US$	0.5682	0.5966	0.6264	0.6578
OPV	Aventis	Finished Product	10	827500	Euro	0.1090	0.1428	0.1496	0.1573
OPV	Biofarma	Finished Product	10	827500	US$	0.1260	0.1314	0.1369	0.1424
OPV	Chiron	Finished Product	10	827500	US$	0.1310	0.1400	0.1500	0.1500
Measles MD	Aventis	Finished Product	10	371650	Euro	0.1510	0.1947	0.2125	0.2227
Measles MD	Biofarma	Finished Product	10	371650	US$	0.1736	0.1736	0.1851	0.1851
Measles SD	Aventis	Finished Product	1	123000	Euro	0.7820	0.9733	1.0608	1.1135
BCG Intradermal	SSI	Finished Product	20	238850	DKK	0.4661	0.4907	0.5153	0.5426

SCHEDULE SA 2 (Page 2 of 3 pages)

(SELLING PRICE IN FOREIGN CURRENCY PER DOSE)

PRODUCT				Quantity		2004	2005	2006	2007
DPT	Aventis	Finished Product	20 or 10	60000	Euro	0.1918	0.2730	0.2970	0.3120
DPT	Biofarma	Finished Product	10	60000	US$	0.1275	0.1275	0.1410	0.1410
DPT	Biofarma	Bulk	20	60000	US$	0.1631	0.1650	0.1841	0.1862
DT	Aventis	Finished Product	20 or 10	110000	Euro	0.1306	0.1740	0.1890	0.1990
DT	Biofarma	Finished Product	10	110000	US$	0.0946	0.0946	0.1031	0.1031
DT	Biofarma	Bulk	20	110000	US$	0.0989	0.1007	0.1107	0.1128
TT	Aventis	Finished Product	20 or 10	290000	Euro	0.1353	0.1965	0.2141	0.2247
TT	Biofarma	Finished Product	20	290000	US$	0.0575	0.0575	0.0609	0.0609
TT	Biofarma	Bulk	20	290000	US$	0.0594	0.0613	0.0662	0.0682
DTPHib	Aventis	Finished Product	10	262250	Euro	2.5540	2.6810	2.8150	2.9560
DTPHib	Aventis	Finished Product	1	897000	Euro	2.9820	3.1310	3.2880	3.4520
HBV ASD	Heber Biotec	Finished Product	1	45755	US$	1.9556	2.0534	2.1561	2.2639
HBV PMD	Heber Biotec	Finished Product	10	375775	US$	0.5644	0.5926	0.6222	0.6533
HBV PSD	Heber Biotec	Finished Product	1	169300	US$	1.1550	1.2128	1.2734	1.3371
HBV ASD	Cheil Jedang	Finished Product	1	45755	US$	0.8750	0.8750	0.8750	0.8750
HBV PMD	Cheil Jedang	Finished Product	10	375775	US$	0.2963	0.2963	0.2963	0.2963
HBV PSD	Cheil Jedang	Finished Product	1	169300	US$	0.6375	0.6375	0.6375	0.6375
HBV ASD	Heber Biotec	Bulk	1	45755	US$	0.7285	0.7649	0.8031	0.8433
HBV PMD	Heber Biotec	Bulk	10	375775	US$	0.5456	0.5728	0.6015	0.6316
HBV PSD	Heber Biotec	Bulk	1	169300	US$	0.7285	0.7649	0.8031	0.8433
OPV	Aventis	Finished Product	10	827500	Euro	0.1282	0.1680	0.1760	0.1850

OPV	Biofarma	Finished Product	10	827500	US$	0.1482	0.1546	0.1611	0.1675
OPV	Chiron	Finished Product	10	827500	US$	0.1541	0.1647	0.1765	0.1765
Measles MD	Aventis	Finished Product	10	371650	Euro	0.1776	0.2290	0.2500	0.2620
Measles MD	Biofarma	Finished Product	10	371650	US$	0.2042	0.2042	0.2178	0.2178
Measles SD	Aventis	Finished Product	1	123000	Euro	0.9200	1.1450	1.2480	1.3100
BCG Intradermal	SSI	Finished Product	20	238850	DKK	0.5484	0.5773	0.6063	0.6384

SCHEDULE SA 2 (Page 3 of 3 pages)

GROSS PROFIT %

PRODUCT				Quantity		2004	2005	2006	2007
DPT	Aventis	Finished Product	20 or 10	60000	Euro	15%	15%	15%	15%
DPT	Biofarma	Finished Product	10	60000	US$	15%	15%	15%	15%
DPT	Biofarma	Bulk	20	60000	US$	20%	20%	20%	20%
DT	Aventis	Finished Product	20 or 10	110000	Euro	15%	15%	15%	15%
DT	Biofarma	Finished Product	10	110000	US$	15%	15%	15%	15%
DT	Biofarma	Bulk	20	110000	US$	20%	20%	20%	20%
TT	Aventis	Finished Product	20 or 10	290000	Euro	15%	15%	15%	15%
TT	Biofarma	Finished Product	20	290000	US$	15%	15%	15%	15%
TT	Biofarma	Bulk	20	290000	US$	20%	20%	20%	20%
DTPHib	Aventis	Finished Product	10	262250	Euro	12%	12%	12%	12%
DTPHib	Aventis	Finished Product	1	897000	Euro	12%	12%	12%	12%
HBV ASD	Heber Biotec	Finished Product	1	45755		20%	20%	20%	20%
HBV PMD	Heber Biotec	Finished Product	10	375775	US$	20%	20%	20%	20%
HBV PSD	Heber Biotec	Finished Product	1	169300	US$	20%	20%	20%	20%
HBV ASD	Cheil Jedang	Finished Product	1	45755	US$	20%	20%	20%	20%
HBV PMD	Cheil Jedang	Finished Product	10	375775	US$	20%	20%	20%	20%
HBV PSD	Cheil Jedang	Finished Product	1	169300	US$	20%	20%	20%	20%
HBV ASD	Heber Biotec	Bulk	1	45755	US$	22%	22%	22%	22%
HBV PMD	Heber Biotec	Bulk	10	375775	US$	22%	22%	22%	22%
HBV PSD	Heber Biotec	Bulk	1	169300	US$	22%	22%	22%	22%
OPV	Aventis	Finished Product	10	827500	Euro	15%	15%	15%	15%
OPV	Biofarma	Finished Product	10	827500	US$	15%	15%	15%	15%

OPV	Chiron	Finished Product	10	827500	US$	15%	15%	15%	15%
Measles MD	Aventis	Finished Product	10	371650	Euro	15%	15%	15%	15%
Measles MD	Biofarma	Finished Product	10	371650	US$	15%	15%	15%	15%
Measles SD	Aventis	Finished Product	1	123000	Euro	15%	15%	15%	15%
BCG Intradermal	SSI	Finished Product	20	238850	DKK	15%	15%	15%	15%