

**AGREEMENT**

between

**Glaxo Group Limited**  
Glaxo Wellcome House  
Berkley Avenue  
Greenford  
UB6 0NN  
UK

("GSK")

and

The Kingdom of the Netherlands  
On her behalf  
Minister of Health, Welfare & Sports  
On his behalf  
The Netherlands Vaccine Institute  
Bilthoven, The Netherlands

("MOH")

regarding

**Supply of Pandemic Influenza Vaccines**

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**TABLE OF CONTENTS**

<b>ADVANCED PURCHASE AGREEMENT .....</b>	<b>3</b>
PREAMBLE.....	3
1.    DEFINITIONS AND INTERPRETATION.....	3
2.    SUPPLY OF PANDEMIC VACCINE.....	8
3.    SUPPLY OF NEW COMPONENTS.....	10
4.    STORAGE, USE AND LABEL CHANGES.....	12
5.    DELIVERY TERMS, RISK OF LOSS AND TITLE.....	12
6.    RELEASE AND VACCINE ACCEPTANCE.....	12
7.    FINANCIAL TERMS.....	13
8.    REGULATORY AUTHORISATION.....	14
9.    SAFETY RISKS AND RECALL OF VACCINES.....	15
10.   IMPORT AND EXPORT.....	15
11.   WARRANTIES.....	15
12.   PRODUCT LIABILITY AND INDEMNITY.....	17
13.   INTELLECTUAL PROPERTY RIGHTS.....	18
14.   LIMITATION OF LIABILITY.....	19
15.   TERM AND TERMINATION.....	19
16.   MISCELLANEOUS.....	20
17.   GOVERNING LAW AND JURISDICTION.....	22
<b>EXHIBIT A - VACCINE SPECIFICATIONS .....</b>	<b>25</b>
.....	29
1.    .....	29
2.    .....	29
3.    .....	29
4.    .....	29
5.    .....	30
6.    .....	30
7.    .....	30
8.    .....	30
9.    .....	31
10.   .....	31
11.   .....	31
.....	32
<b>EXHIBIT D – COMMUNICATION CONCEPT .....</b>	<b>33</b>
1.    CONFIDENTIAL INFORMATION.....	33
2.    PROCEDURE.....	33

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ADVANCED PURCHASE AGREEMENT

PREAMBLE

Terms used in this Preamble are further defined in section 1 below.

- A. Glaxo Group Limited is part of the GlaxoSmithKline group of companies (the "Group"). Affiliates of Glaxo Group Limited develop and manufacture vaccine products for the Group and are developing vaccines against various potential pandemic strains of influenza virus. Glaxo Group Limited owns or controls certain intellectual property rights relating to such potential pandemic influenza vaccines.
- B. Following declaration of phase 6 by the World Health Organisation (WHO) on 11 June 2009, MOH recognizes the need to take suitable measures to increase the level of pandemic influenza preparedness in The Netherlands [REDACTED]
- C. Such vaccine will comprise separate Adjuvant Component and Pandemic Antigen Component, which Pandemic Vaccine is currently approved in Europe as mock-up vaccine based on the A/H5N1/Vietnam influenza virus strain and the Regulatory Authorisation of which shall be varied with such other influenza virus strain of pandemic potential as is technically and commercially feasible and which is recommended by WHO on 11 June 2009.
- D. [REDACTED]
- E. The Parties recognize the urgency of the current public health crisis and are willing to enter into this Agreement. MOH wishes to purchase Pandemic Vaccine on the terms and conditions set out in this Agreement.
- F. MOH is officially mandated by the government of The Netherlands to acquire on its behalf supplies of the Pandemic Vaccine.

Now, therefore, MOH and GSK have agreed as follows:

1. DEFINITIONS AND INTERPRETATION

1.1. Definitions

In this Agreement, unless otherwise specified or inconsistent with the context, the following definitions shall apply:

"Adjuvant Component" means the adjuvant component of the Pandemic Vaccine more particularly described in Exhibit A - Vaccine Specifications.

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[Redacted]

"Affiliate" means any company which Controls, is Controlled by or is under common Control with GSK and/or its ultimate parent company.

[Redacted]

"Agreement" means this agreement including all Exhibits, as amended in accordance with section 16.4 from time to time.

[Redacted]

"Claim" means a claim, complaint, suit, proceedings or cause of action.

"Commercially Reasonable Endeavours" means using all efforts and resources normally used by GSK in the exercise of its business relating to its influenza vaccine products to the extent that the cost of such efforts and resources are commercially viable in connection with the Pandemic Vaccine and taking into account all relevant issues and circumstances including the state of development of the Vaccine, the safety and efficacy of the Pandemic Vaccine, the product profile, the proprietary position of the Pandemic Vaccine, the regulatory structure relating to the Pandemic Vaccine, and other relevant factors, including technical, legal, scientific and/or medical factors.

"Competent Regulatory Authority" means EMEA and the European Commission or Het College ter Beoordeling van Geneesmiddelen as the context allows.

"Component(s)" means the Adjuvant Component and/or the Pandemic Antigen Component as the context allows.

"Control" means the holding, directly or indirectly, of:

- a) more than fifty percent (50%) of the voting share capital of a company; or
- b) the power to appoint at least one half of the Board of Directors or similar body of a company; or
- c) the power, by virtue of the constitution of the company or other arrangements or documents regulating that company, to secure that the affairs of a company are conducted in accordance with the holder's wishes.

"Cross Reactive Immunity" means an immune response against either (a) an H1N1 virus strain of a different clade than the one used in the Pandemic Antigen Component initially supplied under sections 2.2 or 2.3 or (b) a non-H1N1 virus strain in each case as demonstrated by the induction of seroconversion rates



[REDACTED]

**"Customers"** means those countries (or their representative) which, at the time in question, have a contract with GSK or any of its Affiliates for the supply of Pandemic Vaccine for which the Pandemic Antigen Component will be manufactured at the Pandemic Antigen Facility, including MOH during the Term.

**"Delivery" and "Deliver"** means completion by GSK or an Affiliate of all activities of the seller under the definition of the delivery terms in INCOTERMS 2000 set out in section 5.1 at the Place of Delivery.

**"Dose"** means a single dose of Pandemic Vaccines for a healthy adult as specified in the Specifications.

**"Effective Date"** means the date when all Parties have signed this Agreement.

**"EMA"** means the European Medicines Agency.

**"Filling and/or Packaging Facilities"** means the filling facilities and/or the packaging facilities at Wavre and/or Rixensart in Belgium owned and operated by GSK or an Affiliate and/or such other facilities (including third party facilities) as GSK or an Affiliate shall designate from time to time for the filling and/or packaging of the Pandemic Vaccine and references to Filling and Packaging Facilities shall be to any one or more of such facilities.

[REDACTED]

**"Force Majeure"** means any cause preventing GSK and/or its Affiliates from performing any or all of its or their obligations under this Agreement which arises from or is attributable to acts, events, omissions or accidents beyond the reasonable control of GSK and/or its Affiliates including strikes, lock-outs or other industrial disputes (whether involving the work force of GSK and/or its Affiliates, of MOH or of any third party), acts of god, acts of governments, disease (including influenza pandemic), shortage of materials (including suitable hens' eggs and other raw materials), unavailability of transport, war, riot, civil commotion, malicious damage, compliance with any law or judicial order or government or quasi-governmental or other competent institution (including WHO) order, rule, regulation or direction which at the Effective Date are unforeseen and pandemic specific, accident, inability of GSK and/or its Affiliates to operate manufacturing or development activities due to lack of staff as a consequence of a disease, fire, flood, storm or default of suppliers.

**"Good Manufacturing Practice" or "GMP"** means good manufacturing practice in accordance with standards currently required by EU legislation and in particular those set out in its Directive 91/356/EEC, as amended by Directive 2003/94/EC and 91/412/EEC as amended from time to time or other applicable regulation and including in particular the guidelines set out in Volume 4 of EudraLex – The Rules Governing Medical Products in the European Union.

**"Group"** means GSK and all Affiliates.

**"GSK Export"** means GlaxoSmithKline Export Limited, an Affiliate registered as a company in England and Wales with its registered office at 980 Great West Road, Brentford, Middlesex, TW8 9GS, England.

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**"GSK Indemnified Party"** means each of GSK, the Affiliates and their respective officers, directors, shareholders, employees, successors or agents.

**"ICH Guidelines"** means applicable guidelines used by the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use.

[REDACTED]

**"Pandemic Antigen Component"** means the antigen component based on the pandemic influenza virus strain antigen identified by WHO at the time of the pandemic Declaration as shall be more particularly described in Exhibit A - Vaccine Specifications.

[REDACTED]

**"Pandemic Antigen Facility"** means the facilities at Dresden in Germany owned and operated by an Affiliate.

**"Pandemic Antigen Seed"** means the seed for the Pandemic Antigen Component as prepared by a WHO reference laboratory.

**"Pandemic Declaration"** means a declaration by WHO that Phase 6 has been reached with respect to an influenza pandemic.

[REDACTED]

**"Pandemic Facilities"** means in relation to production of the Pandemic Antigen Component, the Pandemic Antigen Facility and in relation to production of the Adjuvant Component the facilities in Belgium owned and operated by GSK Bio or an Affiliate (or in either case such other facilities as GSK may designate from time to time).

**"Pandemic Vaccine"** means the Group's proposed split virus adjuvanted vaccine comprising a separate Adjuvant Component and separate Pandemic Antigen Component, as described in more detail in Exhibit A - Vaccine Specifications and as may be varied from time to time in accordance with this Agreement and references to Pandemic Vaccine shall include a reference to each of the Components, as the context allows.

**"Parties"** means MOH and GSK.

**"Place of Delivery"** means the place of delivery as specified in Exhibit B - Specific Terms.

[REDACTED]

**"Regulatory Authorisation"** means a centralized marketing authorisation (or any Variation thereto) for the Pandemic Vaccine issued by the Competent Regulatory Authority on the basis of Regulation (EC) No 726/2004, or its implementing

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Commission Regulations or Directives, guidelines, etc., or a Temporary Authorisation issued by the Competent Regulatory Authority, as the context dictates.

[REDACTED]

**"Specifications"** means the specifications for the Pandemic Vaccine set out in Exhibit A - Vaccine Specifications and as may be updated or replaced in accordance with this Agreement.

**"Temporary Authorisation"** means an authorisation issued by the Competent Regulatory Authority pursuant to Article 5(2) of Directive 2001/83/EC, as amended by Directive 2004/27/EC and as transposed under the laws of The Netherlands, or any other similar agreement by said Competent Regulatory Authority legally allowing GSK or its Affiliate (a) to manufacture and export the Pandemic Vaccines from Belgium and (b) to supply, place on the market and/or distribute the Pandemic Vaccines to MOH, to import and place the Pandemic Vaccines on the market and/or distribute the Pandemic Vaccines in the Netherlands, in each case without a full and up-to-date centralized marketing authorisation.

**"Term"** means the term of this Agreement set out in Exhibit B - Specific Terms, subject to earlier termination in accordance with section 15.2.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**"Variations"** means such variations to the Regulatory Authorisation for the Vaccine as may be required by Regulation EC/1085/2003 and Regulation 1234/2008.

**"WHO"** means the World Health Organization.

**"Wilful Misconduct"** means an act or omission that is taken (a) intentionally to achieve a wrongful purpose; (b) without legal or factual justification; and (c) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

## 1.2. Interpretation

In this Agreement, the following rules of interpretation shall apply:

- a) references to the singular include the plural and vice versa;
- b) a reference to any law shall include a reference to any revision or re-enactment of that law;
- c) references to persons, individuals, companies, firms, other business entities, unincorporated associations and governmental or supra-national authorities shall include a reference to any of the other entities listed in this sub-section 1.2.c);
- d) references to "days" are to all calendar days including Saturdays, Sundays and bank or public holidays in The Netherlands;
- e) references to "GSK" shall be to Glaxo Group Limited and Affiliates acting together or to each of Glaxo Group Limited and acting severally, as the context admits. Where rights and obligations in relation to the invoicing and payment of the Arrangement Fee and/or Prices are assigned or otherwise

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delegated by GSK to GSK Export or to such other Affiliate whose identity is notified in writing to MOH, references to "GSK" in the context of invoicing and payment of the Arrangement Fee and/or Prices shall be to GSK Export or such other nominated Affiliate;

- f) references to Exhibits are to the exhibits attached to this Agreement, as varied, updated and/or replaced from time to time in accordance with this Agreement; and
- g) references to 'including' shall be construed without limitation.

## 2. SUPPLY OF PANDEMIC VACCINE

2.1 In response to the Pandemic Declaration, the Group has initiated the process of production of Pandemic Vaccine at the Pandemic Facilities [REDACTED]

Release of the bulk antigen and filling of the Pandemic Vaccine into vials shall be subject to GSK's or Affiliate's receipt from the WHO nominated reference laboratory of the Pandemic Antigen Seed's associated calibrated reagents.

Subject to the terms of this Agreement, GSK anticipates the lead times of the pre-production preparation and production of Pandemic Vaccine set out in

[REDACTED]

Without prejudice to the foregoing, MOH agrees that in the specific emergency circumstances of an influenza pandemic, GSK may, at its discretion and subject to section 8.2, change the Pandemic Facilities for production of the Adjuvant Component and/or Filling and/or Packaging Facilities for certain activities, or implement certain process changes relating to the production, filling and/or packaging of Pandemic Vaccine prior to relevant Variations being submitted and approved by the Competent Regulatory Authority. This paragraph is without prejudice to section 8.2.

[REDACTED]

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[REDACTED]

**2.3 Conditions Precedent**

The supply and purchase obligations in respect of the Pandemic Vaccine under section 2.1 or of any New Component under section 3.3 shall be subject to and conditional upon:

- a) GSK or an Affiliate receiving the Pandemic Antigen Seed and associated calibrated reagents from the WHO nominated reference laboratory; and
- b) the Competent Regulatory Authority granting Regulatory Authorisation in respect of the Pandemic Vaccine, subject only to section 8.2;

[REDACTED]

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Immunity vis-à-vis the New Recommended Virus Strain. Should GSK decide to use the New Recommended Virus Strain for the manufacture of Replacement Antigen Component under section 3.1 a) or c), GSK shall notify to MOH the specifications for the Replacement Antigen Component shall be deemed to be added to the Specifications where applicable.

[REDACTED]

**3.2. New Strain Antigen Component**

If (i) at any time during the Term WHO officially recommends and adds a New Recommended Virus Strain and (ii) GSK demonstrates by appropriate assays that the Pandemic Vaccine previously supplied under this Agreement has no Cross Reactive Immunity vis-à-vis the New Recommended Virus Strain then, subject to section 2.3 and section 3.3, MOH may request GSK to supply up to the Aggregate Pandemic Volume of New Strain Antigen Component and MOH shall pay [REDACTED] for such supply.

The specifications for the New Strain Antigen Component shall be added to the Specifications.

**3.3. Provisions applicable to Supply of New Components**

If MOH decides to exercise one of the rights set out in sections 3.1 or 3.2, MOH shall so notify GSK in writing by placing a firm order for the relevant number of Doses of New Component no later than [REDACTED] and MOH shall purchase and GSK shall supply the relevant New Component on the terms of this Agreement. For the avoidance of doubt, GSK shall have no obligation to supply New Components for any Doses of Pandemic Vaccine which has been used or otherwise administered to patients

Upon receipt of the appropriate valid written binding request from MOH for New Components under sections 3.1 or 3.2, GSK will provide an estimated plan for Delivery of the relevant New Components. GSK will use Commercially Reasonable Endeavours to supply the relevant New Components in accordance with this estimated delivery plan as soon as possible.

[REDACTED]

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Board ("CBG") or such laboratory as the CBG shall nominate, (the "Independent Laboratory") for retesting. The decision of the Independent Laboratory shall be final and the costs of such procedure shall be borne by the Party whose opinion is not upheld by the Independent Laboratory.

MOH shall not be entitled to reject any consignment of Pandemic Vaccine except for non conformity with Specification at Delivery. For the avoidance of doubt, MOH shall not be entitled to reject any Vaccine where failure to comply with Specification has been caused by storage conditions or other external factors after Delivery.

**7. FINANCIAL TERMS**

[REDACTED]

**7.3. Taxes and Duties**

Prices and Arrangement Fee stated are exclusive of value added tax. In addition to the Price and Arrangement Fee, MOH shall be fully responsible for paying all indirect taxes, including sales, import, withholding or other taxes or duties including any value added taxes, which may be imposed on the sale or delivery of the Pandemic Vaccine to MOH or otherwise in connection with this Agreement. In view of assessing the taxes that are due, GSK shall inform MOH on beforehand which Affiliate will send the invoice.

**7.4. Invoices and Payment**

[REDACTED]

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If MOH fails to pay any amount when due to GSK or its Affiliate under this Agreement (subject to postponement of the due date for payment under this section 7.4 below):

- a) MOH shall be liable to pay GSK interest on such outstanding amount from the due date at [REDACTED]
- b) If payment is more than sixty (60) days late, GSK may cease delivery of Pandemic Vaccine until payment is made.

If MOH receives an invoice which it reasonably believes specifies an amount which is not valid and properly due (a "**Disputed Amount**"):

- a) MOH will pay the undisputed amount due to GSK within thirty (30) days of the date of the invoice; and
- b) MOH may withhold payment of the Disputed Amount in that invoice provided that MOH shall notify GSK within fifteen (15) days of receipt of the invoice, of the nature of the dispute. The due date for payment of the Disputed Amount shall be postponed and GSK and MOH shall endeavour in good faith to resolve the dispute as soon as reasonably possible.

After resolution of the dispute, MOH will within thirty (30) days of the date of the resolution of such dispute, pay the Disputed Amount or part of the Disputed Amount that in the course of resolution of the dispute has been determined as due to GSK.

## 8. REGULATORY AUTHORISATION

### 8.1. Maintenance of Regulatory Authorisation

GSK shall use Commercially Reasonable Endeavours to obtain and maintain Regulatory Authorisation for the Pandemic Vaccine in the European Union and/or The Netherlands. [REDACTED]

[REDACTED] The Parties shall cooperate in good faith to endeavour to secure Regulatory Authorisation in respect of the Pandemic Vaccine.

The Regulatory Authorisation will be held by GSK or its nominated Affiliate.

### 8.2. Delivery without Regulatory Authorisation

As part of MOH's pandemic preparations, MOH may wish to be supplied with the Pandemic Vaccine prior to grant of Regulatory Authorisation or prior to approval by the Competent Regulatory Authority of any necessary Variations.

If MOH expressly requires in writing Delivery of the Pandemic Vaccine prior to such Regulatory Authorisation and/or approval of such necessary Variations, GSK may, subject to section 12.2 and due to the emergency of the situation and the importance of this public health crisis, produce and supply Pandemic Vaccine notwithstanding that the Pandemic Vaccine may not have received Regulatory Authorisation or the Regulatory Authorisation may not have been duly updated by approval of necessary Variations

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**9. SAFETY RISKS AND RECALL OF VACCINES**

The Parties shall immediately notify each other of any information in relation to the Pandemic Vaccine received regarding any threatened or pending action by any regulatory authority in The Netherlands and/or elsewhere in the European Union.

GSK will investigate and, where appropriate, the Parties will discuss in good faith whether additional terms are necessary in order to facilitate the management of safety for the Pandemic Vaccine in accordance with standards which are no less stringent than in the ICH Guidelines.

If the Parties agree that such additional terms are necessary, they shall negotiate such additional terms as are necessary to enable:

- a) the Parties to comply with regulatory requirements for the reporting of safety data in accordance with standards stipulated in the ICH Guidelines, and all applicable regulatory and legal requirements regarding the management of safety data; and
- b) the Parties to exchange relevant safety data within timeframes and in a format that will facilitate compliance by each of them with both expedited and periodic regulatory reporting requirements; and
- c) GSK to comply with any risk management plans or any other plans for minimizing risks or managing potential safety issues, as may be required by the Competent Regulatory Authority and/or the EMEA in the Regulatory Authorisation for the Pandemic Vaccine or by guidelines from international bodies such as WHO.

If a recall of the Pandemic Vaccine in The Netherlands is required for any reason, GSK in consultation with the Competent Regulatory Authority will be responsible for the coordination and accomplishment of the recall unless the Competent Regulatory Authority in cooperation with MOH wishes to take the lead on such recall. MOH and, where appropriate, GSK shall provide all reasonable assistance, consultation and information reasonably required in respect of any such recall.

**10. IMPORT AND EXPORT**

MOH shall provide all reasonable assistance and information which is necessary or reasonably required for GSK to obtain any manufacturing, export and/or import licences required for GSK to manufacture, export and/or import Pandemic Vaccine. Any information is to be provided within fourteen (14) days of GSK's request.

**11. WARRANTIES**

[REDACTED]

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[REDACTED]

**11.2. Notice of Claim**

MOH may claim a breach of warranty under this Agreement against GSK only by written notice to GSK, submitted within thirty (30) days following the date on which MOH has obtained reasonable knowledge of the existence of such claim and within the warranty period stated for the warranty in question ("Notice of Claim"). The Notice of Claim shall contain in reasonable detail all the relevant facts of the alleged breach and a clear reference to the warranty allegedly breached.

**11.3. Specification, GMP**

GSK warrants to MOH that save as may otherwise be agreed with the Competent Regulatory Authority and/or between the Parties under this Agreement or otherwise, and save where MOH requests GSK to supply Pandemic Vaccine prior to approval of the necessary Variations under this Agreement, the Pandemic Vaccine shall be manufactured, filled, stored, packaged, labelled, released and Delivered in compliance with GMP, to the extent that each standard of GMP is or can be applicable, including in circumstances where there is no Regulatory Authorisation, and shall comply with the Specification for the Pandemic Vaccine at Delivery..

[REDACTED]

The Parties agree that the labelling, primary and secondary packaging of the Components and product information may be solely in English, at GSK's discretion.

[REDACTED]

**11.4. Warranty by MOH**

MOH represents and warrants that:

- a) it is legally entitled and has the full power to enter into this Agreement, to carry out its obligations under this Agreement and to grant the rights and benefits granted by it to GSK under this Agreement and by doing so does not infringe any agreement with any third party;
- b) it has the right to order the quantities of Pandemic Vaccines in accordance with any applicable laws and regulations,
- c) it will use its best efforts to assist GSK in securing prior to any supply of Pandemic Vaccine any and all regulatory approvals (including the Regulatory Authorizations) for the purpose of supply, stockpile and

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administration of the Pandemic Vaccine for all age groups concerned in The Netherlands.

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[Redacted]

[Redacted]

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**13. INTELLECTUAL PROPERTY RIGHTS**

**13.1. Use of Adjuvant Component by MOH**

MOH agrees that, because the exact composition of the Adjuvant Component is confidential and contains proprietary know-how belonging to GSK or an Affiliate and because of relevant third party intellectual property rights:

- a) MOH shall only use, and shall ensure that any third party to whom MOH provides the Adjuvant Component only uses, the Adjuvant Component in a vaccine in conjunction with Pandemic Antigen Component supplied by GSK or otherwise with GSK's consent; and
- b) MOH shall not test, or have tested, the Adjuvant Component. However testing for assessing compliance to the Specifications of the Adjuvant related to the actual administering of the Pandemic Vaccine in humans due to the pandemic shall be allowed; and
- c) without prejudice to (a) above and section 16.4 below, MOH shall not sell, lend, donate, supply to or otherwise permit the use of the Adjuvant Component by any third party other than treating physicians and/or nurses in charge of administering the Pandemic Vaccine to patients and relevant personnel in the distribution chain.

MOH shall indemnify and hold harmless each GSK Indemnified Party against any and all liability, damages, penalties, fines, costs, expenses (including reasonable legal expenses and reasonable expenses of other professionals) and other losses suffered or incurred by any GSK Indemnified Party resulting from or arising out of any breach of this section 13.1.

GSK (or its Affiliates) shall have sole conduct of any litigation and/or negotiations with any person or party making a Claim to which the indemnity in this section 13.1 applies and shall use Commercially Reasonable Endeavours to settle such Claim on reasonable commercial terms. MOH shall provide all reasonable assistance to settle such Claims.

GSK (or its Affiliates) shall promptly notify MOH of any Claim to which the indemnity in this section 13.1 applies.

**13.2. Warranties**

GSK represents and warrants that it and/or its Affiliates:

- a) have made all reasonable enquiries relating to its portfolio of patents and intellectual property rights; and
- b) based on such enquiries and subject to the disclosure made in section 13.1, to the best of its knowledge it is not aware that the manufacture and supply to MOH and use in The Netherlands of the Pandemic Vaccine in accordance with this Agreement infringes or may infringe valid granted patents of any third party.

If GSK is in breach of this warranty MOH may as MOH's sole remedy, seek damages subject always to the limitations of liability set out in section 14 and the procedure set out in section 11.2.

The warranty period for a claim with regard to the warranty in this section 13.2 shall be the Term of this Agreement.



supply of the Aggregate Pandemic Volume to MOH and (b) decision by MOH to use and administer the Pandemic Vaccine for the entire Dutch population..

**15.2. Termination by Either Party**

This Agreement may be terminated by either party if the other Party is in material breach of its obligations under this Agreement and has not remedied such breach within thirty (30) days of receipt from the first Party of written notice requiring remedy of such breach accompanied by the reason why it believes that the other Party is in breach.

[REDACTED]

**16. MISCELLANEOUS**

**16.1. Confidentiality**

MOH undertakes and shall procure that any third party to whom disclosure may be made under this section 16.1 undertakes, for the benefit of GSK, to treat the text of this Agreement and the information set out in section 1 of Exhibit D (the "Confidential Information") as confidential and shall keep it confidential, and shall not disclose such Confidential Information to third parties.

The above obligation shall not apply to Confidential Information to the extent that such information at the time of disclosure (whether such disclosure was or is made before or after the Effective Date):

- a) is, or was, already in the possession of MOH otherwise than following disclosure by GSK;
- b) is, or becomes, public information through no wrongful act by MOH;
- c) is, or was, received by MOH from a third party who is under no legal obligation to maintain the confidentiality of the information, or,
- d) is independently developed by MOH without reliance on the Confidential Information.

The obligation to hold in confidence and not disclose the Confidential Information shall not prevent MOH from disclosing Confidential Information:

- i) on a need-to-know basis to the Competent Regulatory Authority; provided that the scope of disclosure shall be limited to the necessary extent and that MOH shall be responsible that such recipients of Confidential Information shall be bound by terms of confidentiality and restrictions on use that are at least as restrictive as the terms of this Agreement;
- ii) to the extent required by law to any judicial or regulatory tribunal or other entity, or pursuant to a court order, provided that MOH gives reasonable notice to GSK prior to such disclosure and takes account of any proposals that GSK may make to protect GSK's Confidential Information and any disclosure is made in confidence where possible; or



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- iii) to the extent necessary for GSK to comply with its financial or other statutory obligations, including stock market regulations, in The Netherlands or other jurisdictions.

Further details of the communication concept are set out in Exhibit D – communication concept, which may be updated from time to time.

**16.2. Force Majeure**

If and to the extent that GSK and/or its Affiliates are prevented from performing any or all of their obligations under this Agreement because of Force Majeure then GSK and its Affiliates shall be excused performance of their obligations to the extent and for the period required by such cause. If the Force Majeure continues for a period of 12 weeks after first notice of non-performing, MOH shall be entitled, at its sole discretion to terminate the Agreement and any ensuing agreements. MOH shall consequently be released from making any further payments for Vaccines not yet supplied.

**16.3. Relationship of Parties**

The Parties are independent contractors under this Agreement and no other relationship, including partnership, franchise, joint venture, agency, employer/employee, fiduciary, or other special relationship is intended. No Party shall act in a manner which expresses or implies a relationship other than that of independent contractor, nor attempt to bind another Party.

**16.4. Resale**

GSK agrees that MOH may resell, supply or donate the Pandemic Vaccines in and outside the EU. In the event that MOH would decide to resell, supply or donate the Pandemic Vaccines outside the EU, it will confer with GSK on the specifications of the distribution of the Pandemic Vaccines to such countries. Parties agree on the fact that they will work in good faith on further warranties, guarantees, and liabilities on such distribution outside the EU similar to those set out in this Agreement, taken into account that the Pandemic Vaccines are labelled under GSK Trademarks and that such resale, supply or donation shall not be permitted until such agreement has been reached. For the avoidance of doubt, the indemnities under section 12 and /or 13 shall remain fully applicable to any Dose of Pandemic Vaccine resold, supplied or donated by NVI under this section 16.4.

**16.5. Notices**

Notices, provided for in this Agreement shall only be valid if duly signed by the relevant Party and transmitted by registered mail or delivered by hand to the address of the recipient as set out in Exhibit B – Specific Terms.

**16.6. Entire Agreement**

This Agreement contains all the arrangements made between the Parties in connection with the manufacture and supply of the Pandemic Vaccines. It is the intention of the Parties that this Agreement be executed in the English language. In the case of any translation of this Agreement, the English version of this Agreement shall prevail.

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Any amendment of the Agreement and any future representation relating to the Pandemic Vaccine is only valid if made in writing as an amendment to this Agreement and signed by authorized signatories of all Parties.

No terms, conditions or representations endorsed on, delivered with or contained in any purchase order, confirmation of order, specification, correspondence preceding signature of this Agreement or any other document shall be incorporated into this Agreement or construed as a separate contract for the supply and purchase of the Pandemic Vaccine, for any reason.

**16.7. Severability**

- a) Subject to section 16.7 b) should any part of this Agreement be or become or be found by a court, arbitration panel or judicial or administrative body to be void, ineffective or unenforceable for any reason, the validity of the remaining sections of this Agreement shall not be affected. In such a case, the ineffective section or sub-section shall be deemed as replaced by provisions achieving the purpose of this Agreement as far as possible.
- b) If the indemnity and limitation of liability provisions contained in sections 11, 12, 13 and/or 14 are, notwithstanding section 16.7 a) found by a court, arbitration panel or judicial or administrative body to be void, ineffective or unenforceable all supply obligations of GSK under this Agreement shall terminate immediately.

**16.8. Counterparts**

This Agreement may be executed in two counterparts, each of which shall be an original and which together shall constitute one and the same instrument.

**16.9. Assignment**

This Agreement and/or any right and obligation under this Agreement may only be assigned to third parties with the prior written consent of the non-assigning Party save that GSK shall not have to require such consent to assign any rights or obligations to any Affiliate or to any purchaser of all or a substantial part of GSK's or any Affiliate's business. The Parties shall undertake appropriate measures to assign all rights and duties arising under this Agreement to any legal successors they may have.

**17. GOVERNING LAW AND JURISDICTION**

The interpretation and operation of this Agreement and any assessment of the legal validity of the agreed forum for dispute resolution shall be governed by the law of The Netherlands provided that any treaty shall hereby be expressly excluded. The Parties specifically disclaim the UN Convention on Contracts for the International Sale of Goods.

The resolution of any dispute arising out of or in connection with this Agreement shall, save as otherwise agreed by the Parties, be exclusively subject to the rules of the International Chamber of Commerce (ICC), which are incorporated herein by reference, and the arbitral tribunal designated shall have exclusive jurisdiction. Such disputes shall be resolved by final and binding arbitration by the arbitral tribunal in accordance with the substantive and procedural rules of the said arbitration body. The arbitration tribunal shall be composed of three (3) independent arbitrators, each Party nominating one arbitrator and the Chairman of

the panel to be chosen by the other two arbitrators, provided that the Chairman shall be chosen from a list of approved arbitrators of an established international arbitration institution and shall not be of the same nationality as any of the Parties. The arbitration proceedings shall be conducted in English in closed doors and confidential. The venue of the arbitration shall be agreed by the Parties or, if none is agreed within 60 days of a party filing a request for arbitration with ICC, by the arbitral tribunal. The above is expressly without prejudice to, and shall not be construed as a waiver of, the right of any Party to seek injunctive or similar interim relief in any court of competent jurisdiction. Neither Party may seek relief in any court except to enforce such arbitration decision in court or to seek injunctive relief.

**AGREED FOR AND ON BEHALF OF THE PARTIES**

Place, Date: London, 19<sup>th</sup> June 2009

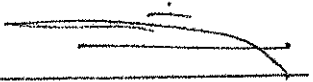
Glaxo Group Limited  
Duly represented by her Corporate Director Edinburgh Pharmaceutical Industries  
Limited  
On her behalf:



██████████  
Authorised Signatory

Place, Date: Bilthoven, 19<sup>th</sup> June 2009

The government of The Kingdom of The Netherlands  
Duly represented by The Netherlands Vaccine Institute  
On her behalf:



██████████  
General Director





## EXHIBIT A - VACCINE SPECIFICATIONS

## 1 Product Composition and specifications on final container

## 1.1 Antigen Component

Split Influenza vaccine of avian strain, inactivated, containing antigen<sup>1</sup> equivalent to:

Pandemic Antigen Component	Pandemic-specific influenza virus strain based on the Pandemic Antigen Seed	3.75 microgram <sup>2</sup>
----------------------------	-----------------------------------------------------------------------------	-----------------------------

<sup>1</sup> propagated in eggs

<sup>2</sup> haemagglutinin content to be confirmed – may depend on what is required for Regulatory Approval

## 1.2 Adjuvant Component

The split antigen is adjuvanted by AS03, which has the following composition per 0.5 ml Dose\*

Squalene	10.69 mg
DL- $\alpha$ -tocopherol	11.86 mg
Polysorbate 80 (Tween 80)	4.86mg

\* definition of 'Dose' based on the actual dosage for a healthy adult

## 1.3 Quality Control

The Pandemic Vaccine will be supplied in 2 separate vials containing Antigen Component and Adjuvant Component respectively.

The specifications for the 2 vial presentation are described in Tables 1 and 2 below.

**Table 1** Release specifications for final containers of Antigen Component

Test	Specification
Description	Colourless light opalescent liquid
Identity Influenza A virus strain	Positive
Sterility	No microbiological growth
Bacterial endotoxins (LAL)	$\leq 200$ EU/ml
pH	6.8 – 7.5
Volume	$\geq 2.5$ ml

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Thiomersal	17 – 23 µg/ml
HA content	15 µg/ml <sup>1</sup>

(1) Ph.Eur.: the confidence limits (P=0.95) are not less than 80% and not more than 125% the estimated HA antigen content. The lower confidence limit (P=0.95) is not less than 80% of the amount stated on the label.

**Table 2** Release specifications for final containers of Adjuvant Component

Test	Specification
Description	Whitish homogenous liquid (milky) emulsion
Identity Polysorbate 80	Positive
Polysorbate 80 content	Between 17.3 and 22.7 mg/ml
Identity $\alpha$ -tocopherol	Positive
$\alpha$ -tocopherol content	Between 42.6 and 54.1 mg/ml
Identity Squalene	Positive
Squalene content	Between 39.0 and 48.4 mg/ml
pH	Between 6.5 and 7.1
Volume	Not less than 2.5 ml
Endotoxin content	Not more than 30 IU per ml
Sterility test	Absence of growth
Particles size	The average particle size is between 140 and 180 nm
Polydispersity index	Not more than 0.20

## 2 Other

### 2.1 Primary Packaging

The vaccine components (Antigen Component and Adjuvant Component) will be supplied in 10 dose glass vials with a rubber stopper. Detailed information on primary packaging will be in English in accordance with the Annex to these Specifications.

### 2.2 Stability

The vaccine will remain stable for the assured shelf life unless:

- it is not stored at a temperature of 2-8 °C;
- it is exposed to light; or
- it is frozen.

### 2.3 Shelf-life

The minimum shelf-life of the vaccine and individual Components is 18 months from the manufacturing date.

### 2.4 Final Packaging

The Pandemic Vaccine will be packed in one final carton box containing the Pandemic Antigen Component packed in a carton box of 50 vials and the Adjuvant Component packed in 2 carton boxes of 25 vials each.. Alternative pack presentations may also be

used in consultation with the Authority. All packaging shall be sufficiently robust to protect the glass vials.

**2.5 Labelling & Product Information**

All labelling and product information will be in English in accordance with the Annex to these Specifications.

**2.6 Storage and Transport**

MOH's, or as the case may be Affiliate's, storage location needs to be GMP-certificated for storage of cold-chain products. The Pandemic Vaccine has to be stored and transported at 2-8 °C. The temperature of the transport has to be controlled and recorded.

**2.7 Administration of the Pandemic Vaccine**

The Pandemic Vaccine has to be administered by the intra-muscular route.

**ANNEX TO EXHIBIT A – GENERIC LABELS**

**Note** -- The generic label of the Pandemic Vaccine will be the similar to the labels below, except that the name of the virus strain of the Pandemic Vaccine will be updated as soon as practicable.

**Antigen vial**

antigen vial  
Jan2009.pdf

**Adjuvant vial**

adjuvantvial  
Jan2009.pdf

**Antigen box**

antigen  
boxJan2009.pdf

**Adjuvant box**

adjuvantbox  
Jan2009.pdf

**Group label outer box (minimum information needed , further customization per destination)**

outerbox shoebox  
Jan2009.pdf

pictogramJan2009.p  
df

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

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[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]



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EXHIBIT D – COMMUNICATION CONCEPT

I. CONFIDENTIAL INFORMATION

[REDACTED]

The following information about the transactions contemplated by this Agreement shall be deemed to be Confidential Information:

- a) [REDACTED]
- b) [REDACTED]
- c) [REDACTED]
- d) [REDACTED]
- e) [REDACTED]
- f) [REDACTED]
- g) [REDACTED]

1.2. Green List

In particular the following information shall not be deemed to be Confidential Information:

- a) Pandemic Vaccine is a 2 component vaccine
- b) The fact that the Pandemic Antigen Component is cheaper than the Adjuvant Component
- c) Reservation of and number of Doses of Pandemic Vaccine
- d) Delivery after Regulatory Authorisation
- e) Delivery without Regulatory Authorisation in case of pandemic threat
- f) Pandemic Vaccine will be produced in Germany and Belgium
- g) Pandemic Vaccine will be approved by the Competent Regulatory Authority and EU authority
- h) Duration of Agreement
- i) General statement re development plan: "GSK is closely working together with experts from MOH during the entire contract period"

2. PROCEDURE

The Parties agree that MOH (or any other agency or office of the Government of The Netherlands) and GSK (or any Affiliate) may issue a press release and/or make a public announcement about the signing of this Agreement and the transactions

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