

**SUPPLY AGREEMENT
FOR INFLUENZA A (H₁N₁) VACCINE**

by and between

State of the Netherlands
(Nederlands Vaccin Instituut, an agency of the Ministry of
Volksgezondheid, Welzijn en Sport / Health, Welfare and Sport,
instituted by decree of 17 October 2006, FEZ-U-2697164, Stcrt (Public
Gazette) 25 October 2006, 208, p. 29),

(hereinafter "Customer")

and

NOVARTIS VACCINES AND DIAGNOSTICS SRL
Via Fiorentina 1,
53100 Siena, Italy

(hereinafter "Novartis")

(together the "Parties")

This Supply Agreement For Influenza A (H₁N₁) Vaccine (hereinafter this "Agreement") is made and entered into as of June 19, 2009 (the "Commencement Date") between the Parties.

WHEREAS, Novartis and its Affiliates carry on the business, *inter alla*, of the manufacture of vaccine for the prevention of influenza virus infection in humans, including vaccine manufactured in connection with a potential pandemic;

WHEREAS, the world is faced with a potential pandemic with respect to the "Influenza A (H₁N₁)" (the "Pandemic");

WHEREAS, Novartis is working to develop Product (as defined below) to protect against Influenza A (H₁N₁) although there is uncertainty around these development efforts, Novartis' ability to successfully develop Product and the timelines for seed virus production and quality and Product scale up and launch;

WHEREAS, Customer is a sovereign nation or regulatory authority thereof who desires to purchase Influenza A (H₁N₁) vaccine to make available to its citizens to help prevent infection in humans resulting from the Pandemic; and

WHEREAS, both Parties recognize that the uncertainty of the successful development of the Product means that Novartis under no circumstance can guarantee that the Product will produce the desired results or be without side-effects but that the Customer is willing to take those risks, given the reputation and good standing of and its confidence in the abilities of Novartis and given the mock up registration for H5N1 by Novartis; and

WHEREAS, given the extreme urgency caused by the pandemic, the timeframe for open, restricted or unrestricted tender procedures with publication of a contract notice cannot be complied with, which circumstances cannot be attributed to the Customer, and therefore the entering into this contract without following a publicly announced tender procedure is justified;

WHEREAS, Novartis is willing to supply to Customer, and Customer wishes to purchase from Novartis, twenty-five million (25'000'000) doses of Product, subject to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the premises, the Parties hereby agree as follows:

Article 1 Definitions

As used herein, the following terms shall have the following meanings:

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"Affiliate" shall mean any company, partnership or other entity that controls, is controlled by, or is under common control with the entity in question. For purposes of this definition only, "control" means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise, or (b) to own, directly or indirectly, 50% or more of the outstanding voting securities or other ownership interest of such entity, provided that, if applicable law requires a minimum percentage of local ownership, control will be established by direct or indirect beneficial ownership of 100% of the maximum ownership interest that may, under such applicable law, be owned by foreign interests.

"Commercially Reasonable Efforts" shall mean a reasonable degree of effort to accomplish a given task, acknowledging that such things as, without limitation: the complex and highly regulated nature of the Product; the timely availability of suitable virus seed strains, standardizing reagents, egg supply and other materials; the yield of the virus strain; the success of necessary clinical trials programs to support safety and immunogenicity data for the Product; the approval of the final product formulation (antigens and adjuvant content);

other reasons relating to the uncertainties of producing a new strain of pandemic Influenza A (H₁N₁) vaccine; and any other currently unknown factors which may delay or render impossible, Novartis' successful completion of the particular task, including without limitations, developing a suitable production process as may be required for a new strain of virus, meeting delivery schedules and obtaining Product and Marketing Authorizations may be beyond the complete control of Novartis.

"Confidential Information" shall mean (i) any information, oral, visual or written, that is disclosed by one Party to the other Party, pursuant to, in contemplation of, or otherwise in connection with this Agreement or comes to the attention of a Party and relates to the Product or the business of the other Party (whether or not such information is expressly stated to be confidential or marked as such), and (ii) the existence and terms of this Agreement.

"EMA" shall mean the European Medicines Agency

"Estimated Delivery Dates" shall mean the estimated dates as set forth in Article 5.2.

"Formulation" shall mean the amount of antigens and adjuvant to be contained in the Product as set out in the Specifications.

"GMP" shall mean 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.

"Marketing Authorization" shall mean the approval by the EMEA necessary for use, marketing and sale of the Product for vaccination in the Territory.

"Product" shall mean the pandemic influenza vaccine, composed of influenza vaccine antigen based on Influenza A/California/7/2009(H1N1) adjuvanted with MF59®, manufactured by Novartis in accordance with the Specification and delivered in presentation of multi-dose vials.

"Product Authorizations" shall mean any license or authorization required to manufacture, export or import the Product for lawful release to the market in the Territory, together with any renewals, replacements, amendments and supplements thereto.

"Product Manufacturing Defect" shall mean any defect of the Product which is attributable to i) production that does not comply with standard GMP or the Quality Control procedure (as defined in European Directive 2001/83/EC and 2001/82/EC) or ii) non-conformity of the Product with the Specifications.

"Product Price" shall have the meaning set forth in Article 5.1.

"Regulatory Authority" shall mean the EMEA and/or the Dutch Medical Evaluation Board (MEB) and any successor thereto, and any other governmental or quasi-governmental entity or body that becomes responsible for granting a Product Authorization.

"Specification" shall mean the composition and qualities of the Product as set forth in the Annex hereto.

"Territory" shall mean the Netherlands.

Article 2 Purchase and Sale of Product; Intellectual Property Matters

- 2.1. Subject to the terms and conditions of this Agreement, Customer shall purchase from Novartis for its own account and in its own name, and Novartis shall sell and use its Commercially Reasonable Efforts to deliver to Customer, twenty five

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million (25'000'000) doses of Product ("hereafter Purchase Order") for use in the Territory in accordance with this Agreement.

- 2.2 Customer is entitled to cancel the Purchase Order subject to the following conditions:
- 2.3 Novartis may from time to time designate any of its Affiliates or third party contractors ("Designee") and may use the resources and facilities of any of them to fulfill any of its obligations under this Agreement. Such Designee shall be subject to the same terms and conditions stipulated in this Agreement. In the event Novartis designates a Designee, all acts, omissions and negligence of said Designee in connection with this Agreement shall be deemed to be the acts, omissions and negligence of Novartis under this Agreement which shall be dealt in accordance herewith.
- 2.4 Product supplied hereunder shall be in a standardized generally acceptable international packaging - including the package inserts- and trade dress unless otherwise required by the Regulatory Authority . For the sake of clarity this means that the Product packaging and/or inserts shall be in the English language.
- 2.5 The influenza virus strain in the Product shall be in accordance with the recommendations made as of the execution date of this Agreement with respect to the Pandemic by the World Health Organization (the "WHO"), the European Medicines Agency (the "EMA") and the United States Food and Drug Administration (the "FDA"), and the United States Centers for Disease Control (the "CDC"), as appropriate.
- 2.6 In an emergency situation, the Parties shall discuss in good faith the possibility of supply to countries outside of the European Union and shall agree on a potential process to follow.
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- 2.8 Customer will provide Novartis a report of doses used in its vaccination program and inventory on hand on December 15, 2009 and March 15, 2010.
- 2.9 Customer hereby acknowledges that it shall not acquire any rights in respect of any trade names or trademarks of Novartis or its Affiliates or of the goodwill associated therewith and that all such rights and goodwill are, and shall remain, vested in Novartis or such Affiliate. No license, express or implied, is granted by this Agreement by Novartis with respect to any of its or its Affiliates' intellectual property.
- 2.10 Customer shall use only the designated trademark to be registered in the Territory by Novartis, or such other trademarks as Novartis may specify, to identify the Product.
- 2.11 Customer shall not (i) make any modification to the Product or its packaging or (ii) alter, obscure, remove or tamper with any trademarks, markings, numbers, labels, indication of the source of origin, or other means of identification used on or in relation to Product.
- 2.12 To the best of Novartis' knowledge and belief the exercise of the rights granted to Customer under this Agreement will not infringe any patent or other legally protected intellectual property rights of any third party in the Territory. Novartis makes, however, no representation nor gives any guarantee or warranty to this effect.

If the use or sale of the Products by Customer in the Territory results in any claim of intellectual property rights infringement against Customer, Customer shall promptly notify Novartis in writing setting forth the facts of such claims in reasonable detail. Novartis shall have full responsibility for and control of the defence to any such claims, and shall be liable for the entire expense of defending such claims or actions, including the amount of any money judgement rendered against Customer.

Article 3 Shipping and Delivery; Risk of Loss and Transfer of Title; Shelf-Life; Audit and Inspection

- 3.1. Novartis shall use Commercially Reasonable Efforts to deliver the Product as close as possible to the Estimated Delivery Dates set out in Article 5.2, however, it cannot guarantee delivery by such dates. In the event that deliveries are not

possible on or before these dates despite the fact that Novartis has used all Commercially Reasonable Efforts to do so, Novartis shall bear no liability or penalty resulting from such delay in delivery.

- 3.2 Novartis shall be deemed to have fulfilled its obligation to deliver when Novartis shall have made the Products "available" to the Customer for pickup at Novartis designated manufacturing facility's gate in Italy ("the Delivery Point"). Novartis, as a service to and on request of the Customer, may assist the Customer in identifying a trusted carrier, without taking any risk or responsibility for the transport of the Product. Customer shall perform a visual inspection or shall request its carrier to perform such inspection upon delivery of the Product by Novartis. Any defect identified during such inspection shall be immediately reported to Novartis in writing. For the purpose of this section "available Product" means a Product that has been released for use in the Territory and for which all the necessary documents as defined in Directive 2001/83 and 2001/82 for (batch) release to the market in the Territory are included.
- 3.3 In the event that Customer does not collect the Products delivered within forty-eight (48) hours (two (2) working days) after the time designated in written notice pursuant to Article 5.2, Novartis shall at its sole discretion either reallocate the Product to another customer or deem the product accepted by Customer and invoice accordingly and store the product at the Customer costs which shall amount to _____.
- In the case of reallocation of Product, Customer shall have to wait for the next delivery to collect Products again.
- 3.4 In the event that supply of the Product is not available on the Estimated Delivery Dates the Parties shall discuss in good faith a timeframe agreeable to both Parties for later delivery or the possibility for Novartis to supply Customer using Commercially Reasonable Effort to substitute the Product, either with the Flu Cell Culture (A) H1N1 adjuvanted vaccine produced in Marburg or with the egg based (A) H1N1 adjuvanted vaccine produced in Liverpool. This and the "Early Termination" as set forth hereunder shall represent the sole and only remedies available to Customer in the event of non-delivery of Product on or before the date(s) set forth in Article 5.2
- If Novartis foresees a significant delay in the delivery schedule, it will timely inform Customer thereof. If it appears that Novartis would not be able to deliver according to the Estimated Delivery Dates, and the Parties cannot agree on a new timeframe as aforementioned, Customer is entitled to cancel the Purchase Order in full or partially depending on the Product already delivered ("Early Termination") without incurring any cancellation fee subject to the conditions that the delay endures longer than thirty (30) days, that a mutually agreed solution cannot be initiated by Novartis within such period and that Novartis has not used its Commercially Reasonable Efforts to deliver according to the Estimated Delivery Date. ¶

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- 3.5 Title to, and risk of loss of, Product shall pass to Customer upon delivery thereof by Novartis to the Delivery Point, provided that risk of loss and title of any Product properly rejected by Customer pursuant to Article 4.3 shall revert to Novartis immediately upon such proper rejection.
- 3.6. The Products will be delivered EXW Inco terms 2000, accordingly the costs of delivery, shipping and importation of the Product into the Territory, including, without limitation, permits, customs, tariff, tax and import duties, shall be borne by Customer.
- 3.7. Novartis shall deliver to Customer, contemporaneously with or prior to each delivery of Product in accordance with Article 3.5, a Certificate of Analysis, EU batch release certificate and a description of the production process and methods of analysis (Summary Protocol) applicable to such Product.
- 3.8 The shelf-life of the Product to be delivered will be determined by the EMEA and is expected to be based on the mock-up dossier for Focetria® , the shelf-life of which is currently twelve (12) months. The remaining shelf-life of the Product when Delivered to Customer will be at least two thirds of the shelf life as approved by the EMEA. The expiry date shall be shown on the packing, on the certificate of analysis and on the batch release certificate.
- 3.9 If the circumstances of the outbreak of the pandemic virus are such that Parties agree that delivery should be expedite in order to safeguard (timely) supply, parties will meet to discuss the conditions of such deliveries. If necessary, appropriate quality assurance agreements with the appropriate and capable entities shall be negotiated .
- 3.10 Audit and Inspection.

Understanding that the mock-up dossier on which the Product is based as well as the manufacturing facility have been approved by the EMEA, Novartis shall grant to Customer a right to audit under exceptional circumstances those parts of Novartis's Facility at which Product is manufactured and tested. Such audit will take place pursuant to an audit plan provided by Novartis which shall define the date and the duration of the audit. However, Customer will be entitled to perform additional audits immediately upon giving notice in the event of complaints, quality issues, or other enquiries by regulatory authorities.

Customer will discuss the results of any audit with Novartis. Novartis undertakes to perform any requested corrective actions resulting from the observations during

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the inspection as soon as reasonably feasible. Novartis shall bear all costs resulting therefrom or connected therewith. Novartis will report to Customer about his efforts in the carrying out of the corrective actions within an agreed time frame.

In the event that the manufacturing of the antigens or of the adjuvant or the fill-finish is performed by a third party, Novartis shall use its Commercially Reasonable Efforts to ensure that Customer may under exceptional circumstances and for good reasons inspect the third party's premises.

During the course of the contract, Customer reserves the right to perform a vendor rating according to NVI SOP-20098, which SOP will be provided by Customer. Supplier shall offer the necessary support to enable Customer to perform the vendor rating in a proper way.

- 3.11 Customer and Novartis will each nominate a project manager to discuss Novartis' progress in the proper performance of this Agreement as regards the production of the Products under GMP, regulatory issues, delivery and other logistics and safety issues. Project Managers shall be exchanging information regularly.

Article 4 Warranties; Product Inspection; Indemnification; Insurance

- 4.1. Novartis warrants that (i) all Product supplied to Customer shall at the time of delivery conform to the Specification, (ii) Novartis' quality control procedures shall have been materially carried out prior to delivery of all Product and (iii) all Product are manufactured, filled, stored, packaged, labeled, released and delivered in compliance with GMP. _____

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- 4.3. Customer shall as soon as possible, but not later than five (5) calendar days from the date of delivery of the Product to the trusted carrier, conduct an external physical inspection and review the temperature records of the Product and notify Novartis of any issue or physical damage which is apparent from such inspection and review. It is understood that any visual defect identified during the Customer inspection shall be deemed to have been caused during transport, unless otherwise demonstrated by Customer. If Customer fails to give such notice, then the Product shall be conclusively presumed to be accepted by Customer and Novartis shall have no liability or further obligation to Customer in relation to the Product with respect to the temperature records or other Product Manufacturing Defects that could have been identified by such inspection or review. For any Product Manufacturing Defect or physical damage that is not identifiable from such inspection within five (5) calendar days of delivery, the Customer will be obligated to notify Novartis in writing within three (3) calendar days following discovery of the Product Manufacturing Defect or physical damage in order for such Product Manufacturing Defect or physical damage to remain grounds for rejection of the Product, provided that Novartis shall not be liable for any Product Manufacturing Defect or physical damage that is not reported to it within six (6) months after the date of delivery of the Product regardless of whether Customer could have identified such Product Manufacturing Defect or physical damage prior to such date.
- 4.4. Upon receipt of notification from Customer of any Product Manufacturing Defect or physical damage, Novartis shall conduct an investigation. If Novartis agrees with Customer's determination, then, at Customer's election, (i) Novartis shall use Commercially Reasonable Efforts to supply replacement Product to Customer on a timeframe mutually agreed to by the Parties or (ii) Novartis shall issue to Customer a credit note (or refund) for the Product Price paid by Customer to Novartis in accordance with the terms hereof with respect to such Product (in which event Novartis shall not be deemed to be in breach of this Agreement or have any further contractual liability to Customer). If Customer provides written notice of defective or damaged Product within five (5) calendar days of delivery and no Product Manufacturing Defect or physical damage to Product exists, then Customer shall be deemed to accept the Product and shall be obligated to pay the applicable Product Price therefor in accordance with the terms of this Agreement in addition to any storage cost - as set forth in Article 3.3- or disposal costs and Novartis shall not be deemed to be in breach of this Agreement or have any further contractual liability to Customer. It is clearly understood that acceptance of the Product by Customer does not affect Novartis' product liability caused by the Product pursuant to article 9 of this Agreement.
- 4.5. Novartis shall indemnify, defend and hold Customer harmless from all claims, actions, causes of action, liabilities, losses, costs and expenses (including reasonable attorneys' fees) or damages (collectively, "Losses"), which Customer

may be held liable to pay as a result of claims or suits arising out of any injuries to person and/or damage to property to the extent such Losses are caused by Product Manufacturing Defect. This indemnification does not include the event wherein the defects have been caused by or are attributable to events which occurred after delivery of the products by Novartis to Customer or by improper presentation, storage or use of the Product by Customer or other agents of Customer and/or the Dutch Government.

- 4.6. Customer shall indemnify, defend and hold Novartis harmless from all Losses which Novartis may be held liable to pay as a result of claims or suits arising out of any injuries to person and/or damage to property caused by the Product except to the extent such Losses are caused by Product Manufacturing Defect
- 4.7. It shall be a condition of a Party being liable under the foregoing indemnities for claims brought against such Party by third parties that:
- (a) the Party seeking indemnification (the "Indemnified Party") shall notify the other Party promptly of any claims or suits involving the other Party (the "Indemnifying Party");
 - (b) the Indemnified Party shall not accept any compromise or settlement or take any other material steps in relation to the subject of such claim without the prior written approval of the Indemnifying Party;
 - (c) the Indemnifying Party shall be entitled to assume the defense of any claim, including selection of attorneys, and the Indemnified Party shall cooperate fully with, and give every reasonable assistance to, the Indemnifying Party in the investigation and handling of any claim; and
 - (d) the Indemnified Party shall take all reasonable steps, but shall not be obligated to incur any expense in doing so, to mitigate any loss in relation to any claim made against the Indemnifying Party hereunder.
- 4.8. The Parties agree and acknowledge that neither Party shall be liable to the other Party for any damages of any kind incurred by the other Party of an indirect, special, punitive, exemplary or consequential nature; provided, however, that, subject to any other provisions of this Agreement to the contrary, this exclusion is not intended to, nor shall it, exclude actual or compensatory damages of the other Party, including special, punitive, exemplary or consequential damages, owed to third parties as a result of a third party claim.
- 4.9. The Parties acknowledge the necessity of keeping each other informed of all reports of adverse drug events coming to either Party's knowledge with regard to the Product, accordingly the Parties shall use best endeavors to agree and put in place a pharmacovigilance reporting process and related measures at least one month prior to the Customer administering the first vaccination.

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- 4.10 Novartis grants to Customer the right to perform clinical trials and other testing on the Product, with the exception of comparative head to head studies ("Study"), provided that (i) the Customer informs Novartis of such intention in advance in writing and (ii) Customer submits to Novartis the clinical and testing protocols to allow Novartis to comment on the design. All data, information and documents resulting from or arising out of the Study shall be the property of Customer. The Customer shall grant Novartis the right to use such data for any purposes, including but not limited to regulatory, publishing purposes, with no further payment or other obligation. Any invention, suggestion, idea or innovation made by Customer, its employees and agents and any other persons assisting with the conduct of the Study shall be the property of Novartis if it relates directly to the Product and to the extent such invention, suggestion, idea or innovation cannot be exploited without infringing Novartis background intellectual property rights on its Product. Any other invention, suggestion, idea or innovation made by Customer, its employees and agents and any other persons assisting with the conduct of the Study ("Other IP") shall be the property of Customer, but Customer shall grant a non-exclusive, fully paid-up, royalty free, perpetual and irrevocable license to Novartis with the right to grant sublicenses to such Other IP, excluding Customer's background intellectual property rights and know-how. In addition the Customer shall give the right to Novartis to access and use any and all clinical, epidemiological and efficacy data that the Customer would collect while using the Product, subject to any restrictions imposed by the Data privacy law and any other regulatory requirements
- 4.11. Customer shall observe and comply with all storage, handling, stock control and operational requirements relating to Product as set forth in the Specification or otherwise required by the Product labeling, applicable law or regulation.
- 4.12. Novartis warrants that it has appropriate and adequate insurance or self-insurance in the amounts sufficient to cover product liability event or linked events. Novartis shall supply Customer with a copy of such insurance policy on reasonable request.

Article 5 Prices, Delivery Dates and Payment

- 5.1. All prices stated herein are in Euros, excluding VAT as well as all costs related to shipping and importation of the Product into the Territory, including, without limitation, permits, customs, tariff, tax and import duties, which shall be borne by Customer. The price(s) for the Product ("Product Price") are as follows:

<u>Product Presentation</u>	<u>Quantities</u>	<u>Product Price (Euro)</u>
multi-dose* vials	17 million doses	

multi-dose vials*	8 million doses	
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*The number of vials to be supplied shall depend on the final Formulation. Appropriate adjustments will be made to ensure that the number of vials to be supplied and the dosage to be administered meet the quantity of doses ordered.

- 5.2 The Estimated Delivery Dates shall be :
 17 million doses by
 8 million doses by

The delivery dates set out in the table above are provided on an indicative basis only and cannot be guaranteed; however, Novartis shall use its Commercially Reasonable Efforts to provide the Product starting as early as possible. Novartis shall establish the delivery schedule and shall inform Customer two (2) weeks ahead or a mutually agreed time ahead of the delivery time in writing.

- 5.3. In the event that the Influenza A (H₁N₁) strain changes such that WHO declares a new stage 6 pandemic alert for an antigenically drifted virus strain or if there is an antigenic shift to a different Haemagglutinin subtype; the following options, subject as below, are available:

5.3.1. If the Customer's Product order is still in unformulated bulk form, then subject to the Product under the original order showing no cross-reactivity (as judged by CHMP criteria) against the antigenically drifted or shifted virus strain, then, subject to the terms and conditions of this Agreement, Customer may purchase the same amount of antigen doses for the new strain for

5.3.2. If the original Product has been formulated and/or delivered to Customer before the WHO announces the drifted or shifted strain, Customer will be obligated to take and pay for their ordered quantity of Product, but may in addition, subject to the terms and conditions of this Agreement, purchase an equal number of doses of vaccine against the new strain (once produced) subject to the Product under the original order showing no cross-reactivity against the antigenically drifted or shifted virus strain and such order being placed by June 5th 2010.

- 5.4 a) Novartis shall issue invoices to Customer at the end of each month in which Product has been made available in accordance with Article 3.2:

b) Customer agrees to pay the invoice within thirty-five (35) days after receipt of the invoice provided that the invoice is issued in accordance with aforesaid conditions.

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5.7 Subject to Articles 4.2 and 4.4, all payments made by the Customer are non-refundable. All payments to be made hereunder shall be made in Euros by wire transfer in immediately available funds to an account designated by Novartis.

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Article 6 Force Majeure

- 6.1. Neither Party shall be under any liability to the other, nor shall there be a breach of this Agreement, for failure or delay in the performance of any of its obligations hereunder to the extent that such performance is prevented by reason of force majeure.
- 6.2. Upon the occurrence of a force majeure, a Party experiencing the force majeure shall deliver a notice to the other Party within ten (10) calendar days of such occurrence, detailing the nature of the force majeure and when such Party estimates the force majeure shall end if it is possible to estimate.
- 6.3. If the Party invoking the Force Majeure exception is not able to resume performance of its obligations under this Agreement within the estimated timeframe proposed, the other Party is entitled to terminate the Agreement with a sixty (60) days prior written notice.
- 6.4. In this Agreement the expression "Force Majeure" shall mean any cause preventing or hindering the performance of this Agreement arising from or attributable to acts, events or circumstances beyond the reasonable control of the Party affected, including but not limited to epidemic or pandemic of disease, act of God, earthquake, shortage of materials, war, labour disputes, accidents, acts of terrorism, explosion, flood, earthquake, tornado, hurricane, fire, civil disorder, sabotage, riot, civil commotion, breakage or failure of machinery or apparatus, acts taken in connection with national defense requirements, acts of any government authority (including the FDA, CDC and EMEA) (except, in the case of Customer, acts of any government authority in the Netherlands) acts of any supra-national authority (including the WHO), late delivery of seed strain by the WHO, low production yields, unavailability of egg supply, other reasons relating to the uncertainties of developing and/or producing a new strain of pandemic Influenza A (H₁N₁) vaccine or acts taken in compliance with any requests, laws, rules, regulations, orders or actions of any such authority.

Article 7 Term and Termination

- 7.1. The term of this Agreement shall commence as of the Commencement Date and shall expire (i) fourteen (14) calendar days following delivery of all Product hereunder and payment therefor in accordance with the terms hereof; or (ii) upon cancellation of a Purchase Order by Customer, unless earlier terminated in accordance herewith or renewed by mutual written agreement of the Parties.

7.2 This Agreement may be terminated (i) upon mutual written agreement of the Parties, (ii) by Customer in the event of Early Termination pursuant to Article 3.4; (iii) by either Party in the event of a material breach of this Agreement by the other Party which material breach is not cured within ninety (90) calendar days of receipt by the breaching Party of written notice from the other Party of its intention to terminate which notice shall include a description of the alleged breach (iv) in the event of a Force Majeure case pursuant to Article 6. For the sake of clarity, the inability of Novartis to supply Product on the Estimated Delivery Dates shall not be deemed a material breach.

7.3 Upon expiration or termination of this Agreement for any reason other than a material breach on the part of Novartis or Early Termination pursuant to Article 3.4 (i) Novartis shall be relieved from any further obligation to supply or deliver Product and Customer shall remain obligated to pay for all Product produced on its behalf or supplied and delivered to it in accordance with this Agreement prior to such expiration or termination, and (ii) Customer obligation to pay the amount due for cancellation as set forth in Article 2.2 shall continue in force until payment has been received and (iii) Article 5.3.2 shall survive until June 5th, 2010 to cover the option of buying a new product at a discounted price, except if this Agreement is terminated by Novartis for material breach on part of Customer, (iv) the Parties' indemnification obligations under Article 4 shall continue in full force until expiration of the applicable statute of limitations, and the Parties' obligations under Article 8 shall continue in full force and effect for a period of seven (7) years following such expiration or termination as well as any other provision that is meant to survive.

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Article 8 Confidential Information

8.1. Except as provided herein, each Party (i) shall keep all Confidential Information of the other Party confidential and accordingly shall not disclose such Confidential Information to any other person or entity, and (ii) shall not use any Confidential Information of the other Party for any purpose other than the performance of its obligations under this Agreement. Confidential Information may be disclosed by a Party only as follows: (a) to the extent required by applicable law or regulation, by the legal process or by request of a governmental

authority, (b) to any employees, attorneys or consultants of a Party who have a need to know such information in the course of their duties, (c) in connection with any legal or other proceedings between the Parties, (d) to the extent that it can be reasonably shown that such Confidential Information is as of the Commencement Date, or hereafter becomes, public knowledge through no act or omission of such disclosing Party (provided that in so demonstrating the disclosing Party shall not disclose any Confidential Information which is not public knowledge), (e) to the extent such Confidential Information can be reasonably shown by such disclosing Party to have been known to such party Prior to its being disclosed by the other Party and f) to the extent such Confidential Information can be reasonably shown to have been independently developed by such disclosing Party without use, directly, or indirectly, of any Confidential Information of the other Party, and subject in every preceding case that the disclosing Party uses its best efforts to ensure that the person or entity to whom any such Confidential Information is disclosed keeps such Confidential Information confidential and does not use the same except for the purpose for which the disclosure is made.

- 8.2. For the avoidance of doubt the existence of this Agreement and the terms, incorporated herein shall be deemed confidential Information and treated in accordance with Article 8.1 above.

Article 9 Product Liability

- 9.1. Normal product liability laws and regulations within the Territory shall apply when the Product is used strictly within the scope of its Marketing Authorization, once it is available. Novartis shall bear no liability for the use of the Product outside of the indication of the relevant Marketing Authorization, for the use of the Product before such Marketing Authorization is granted, for the use of the Product contrary to the specific recommendations in the Product labeling, or for the use of Product which has been handled other than as indicated in the Product labeling, in each case, regardless of whether the Product is labeled with generic or specific trade dress and of the language used in the labeling.

Article 10 Miscellaneous

- 10.1 This Agreement may not be modified or amended except with the consent in writing of both Parties. Neither this Agreement nor either Party's rights or obligations hereunder may be assigned without the prior written consent of the other Party, provided that Novartis may assign this Agreement and/or its rights and obligations hereunder to any Affiliate without the prior written consent of Customer.
- 10.2 In the event of a controversy or claim arising out of or relating to this Agreement or a breach thereof, the Parties shall try to settle those conflicts amicably between themselves. Should they fail to agree, each Party shall be entitled to seek any remedy available to it under applicable law.

- 10.3 Neither Party shall issue press releases or make public announcements relating to this Agreement without the other Party's prior written approval, which approval shall not be unreasonably withheld or delayed.
- 10.4 This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes all previous communications or representations, agreements or understandings whether oral or written between the Parties.
- 10.5 All notices which are required or may be given hereunder shall be in written or electronic form, and shall be deemed delivered (a) on the date of delivery when (i) delivered by hand or (ii) sent by reputable overnight courier maintaining records of receipt and (b) on the date of transmission when sent by facsimile or other electronic transmission during normal business hours with confirmation of transmission by the transmitting equipment (if confirmed by delivery in a method described in clause (a) within three (3) calendar days after its delivery by facsimile or other electronic transmission).

Novartis

Customer

Lucas Elting
General Director
Antonie van Leeuwenhoeklaan 11
Postbus 457
3720 AL Bilthoven
The Netherlands
Phone: + 31 30 2743088
Fax: + 31 30 2287874
Email: lucas.elting@nvi-vaccin.nl

- 10.6 Customer is of the view that this Agreement has been entered into in accordance with EU and Dutch procurement law. Customer shall hold Novartis free and harmless for any direct damages, should it, according to a decision by a competent court in final instance, be ruled that this Contract is nil and void or that this Contract is to be terminated by the Customer in lieu of a public tender to be organised by the Customer.
- 10.7 This Agreement shall be governed and construed in accordance with the laws of The Kingdom of the Netherlands (without regard to conflicts of laws). All disputes in connection with this Agreement or any agreements in connection with this Agreement, which cannot be amicably settled by the Parties themselves and

which are deemed to be a dispute by either of the Parties, shall be finally settled by binding arbitration in accordance with the then current Rules of Arbitration of the International Chamber of Commerce (ICC).

The place of arbitration shall be Geneva. The language of the arbitration shall be English. The number of arbitrators shall be three (3). Each party will nominate one (1) qualified arbitrator; and the two (2) arbitrators so nominated shall nominate a third qualified arbitrator, who shall be the presiding arbitrator, in each case subject to confirmation by the International Court of Arbitration of the International Chamber of Commerce (the "ICC Court"). In the event either Party shall have failed to nominate a qualified arbitrator as provided above within fifteen (15) business days after the other Party shall have nominated its arbitrator, or the two arbitrators so nominated shall fail to agree on a third arbitrator as provided above within thirty (30) days, the presiding arbitrator shall be appointed by the ICC Court.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives:

FOR NOVARTIS VACCINES AND DIAGNOSTICS SRL

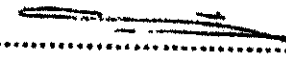
Signature:

Name:

Title:

Date:

**FOR STATE OF THE NETHERLANDS (NEDERLANDS VACCIN
INSTITUUTM, AN AGENCY OF THE MINISTRY OF VOLKSGEZONDHEID,
WELZIJN EN SPORT/ HEALTH, WELLBEING AND SPORT)**

Signature: 

Name: *L. Etting*

Title: *General Director*

Date: *June 19 2009*

ANNEX

Specification

The Product shall mean the pandemic influenza vaccine, composed of influenza surface antigen derived from A/California/7/2009(H1N1), adjuvanted with MF59®, manufactured by Novartis in accordance with the Specification as follows:

Physical, Chemical and Pharmaceutical Properties

Description of Drug Substance

The active ingredients of the vaccine are egg or MDCK cell culture derived H1N1 influenza virus surface antigens (hemagglutinin and neuraminidase) of an A/California/07/2009 like strain as recommended by the World Health Organization (WHO)

The potency of the vaccine is expressed as the concentration of the hemagglutinin (HA) protein.

The Drug Substance is a sterile suspension containing predominantly the purified outer membrane proteins, hemagglutinin (HA) and neuraminidase (NA), of an influenza virus strain with a pandemic potential. Elements of the viral envelope may be present in traces.

Formulation of Drug Product

The Vaccine is a cell culture or egg derived monovalent influenza H1N1sw vaccine (surface antigen, inactivated, adjuvanted with MF59). The vaccine is presented as a white homogeneous suspension.

The MF59 adjuvant is an oil-in-water emulsion, composed mainly of squalene that is an intermediate metabolite in the synthesis of cholesterol.

The formulation is anticipated to comprise any of the following:

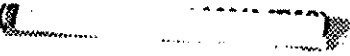

- an injection volume of 0.5mL 
- an injection volume of 0.25mL 

Table: Formulation of batches regarding HA and MF59

Group - formulation	Vaccine formulation			Final Dose Volume (mL)
	Antigen content (in µg)	MF59 content		
		(in mg)	(in %)	
A				
B				

???

Ingredients	Quantity per dose	Function	Reference to Standards
Active Ingredient			
1			
2			
3			
4			
5			
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7			
8			
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10			
11			
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* HA = Haemagglutinin

Stability

Stability data for the investigational egg-based MF59 adjuvanted formaldehyde-inactivated monovalent H5N1 vaccine Aflunov®, and the FCC-based non-adjuvanted seasonal Optafu® vaccine are available. Aflunov has a good stability profile for up to 24

months at 2-8°C and is comparable to the profile of the seasonal Flud[®] vaccine. Optafu[®] vaccine has a good stability profile for up to 18 months at 2-8°C. The FCC H5N1 Phase I/II clinical trial material stability can also be used as supportive data. All this data for similar formulations support the stability of the FCC H1N1sw + MF59 vaccine.

Novartis will test the stability of the antigen bulk formulation without MF59 and including 100% MF59 filled in multi-dose vials in line with CHMP requirements.